CORE OUTCOME SET DEVELOPMENT FOR CLINICAL TRIALS: UNDERSTANDING HOW QUALITATIVE RESEARCH APPROACHES CAN HELP TO ACCOMMODATE OUTCOMES THAT ARE IMPORTANT TO PATIENTS

BY

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Abstract

The thesis aims were twofold (1) to understand how qualitative approaches can inform Core Outcome Set (COS) development and (2) to compare the utility of three qualitative data collection methods for understanding which outcomes are important to patients.

Firstly, a review examining the participation of patients in COS development and the use of qualitative research was conducted. Secondly, evidence from studies comparing the use of face-to-face and online focus groups was reviewed. Finally, the outputs of qualitative data collected from adult burns patients using (1) face-to-face focus groups (2) online focus groups, and (3) interviews, was compared according to the outcomes elicited, sample characteristics, depth of data and resource use.

The first review demonstrates that whilst patients and carers participated in outcome elicitation for COS development, professionals were overly represented in prioritisation exercises. Of 10 qualitative papers identified only 3 were a clearly pre-designed component of the COS. The second review suggests that both face-to-face and online focus groups have advantages dependent on the context for their use. A similar range of outcomes relevant to adult burns patients were identified regardless of the qualitative data collection method. Whilst interviews produced more in-depth data, online focus groups used the least resource.

Dedication

I dedicate this work to my father LEONARD DAVID EMERY who sadly passed away in December 2016.

"My father gave me the greatest gift anyone could give to another person, he believed in me".

Jim Valvano, American College basketball player, coach, and broadcaster.

I also dedicate this work to my daughter KATIE CHRISTINA JONES. She is a constant source of pleasure and delight and I am immensely proud of all she has achieved.

Last, but not least, I dedicate this research to my friend and colleague Dr. GEORGE DOWSWELL who sadly passed away in 2016. I will be forever grateful for his support and encouragement without which I would never have had the confidence to apply for this Ph.D.

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"If you get any opportunity, take advantage of it. And if you start anything never quit"

Julio Jones, Wide Receiver (Atlanta Falcons)

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Contribution statement

All the chapters in this thesis are the product of my own work. My supervisors provided support and guidance with the design of the research, the data analysis, the interpretation of the findings, the write up and critical review and feedback on the thesis.

Dr. Tom Keeley, research fellow, helped with data extraction, validation and the drafting of the manuscript for the first literature review (see Chapter 2: A review of patient and carer participation and the use of qualitative research in the development of core outcome sets).

Fay Gardiner, University Hospitals Birmingham NHS Foundation Trust and Janine Evans, the Morriston Hospital, Swansea and Alison Guy North Bristol NHS Trust helped with the identification and recruitment of participants to the face-to-face focus groups (see Chapter 4: Methodology and methods, and Chapter 5: What outcomes are important to adult burns patients that have experienced scar management therapy? Insights from different qualitative data collection methods).

Thesis format

Chapter 3 of this thesis is the published literature review paper:

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List of abbreviations

Abbreviation	Description
CASP	Critical appraisal skills programme
COMET	Core Outcome Measures for Effectiveness Trials
CONSORT	Consolidated Standards of Reporting Trials
COS	Core Outcome Set(s)
COS-STAR	Core Outcome Set – Standards for Reporting
FG	Focus group
GB	Great Britain
GCP	Good Clinical Practice
GP	General Practitioner
GT	Grounded Theory
IPA	Interpretive Phenomenological Analysis
HCP	Healthcare Professional
HRA	Health Research Authority
NHS	National Health Service
OT	Occupational Therapist
OMERACT	Outcome Measures in Rheumatology Clinical Trials
OSCAR study	What outcomes matter to adult burns patients that have received scar management therapy?
PICO	Patient, Intervention, Comparator, Outcome
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRO	Patient-Reported Outcome
PROM	Patient-Reported Outcome Measure
PROMIS	Patient-Reported Outcome Measurement Information System
PTSD	Post-Traumatic Stress Disorder
R&D	Research and Development
RCT	Randomised Controlled Trial
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
SPIRIT-PRO	Standard Protocol Items: Recommendations for Interventional Trials – Patient-Reported Outcomes
SSCI	Social Sciences Citation Index

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Publications

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Poster presentations

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CHAPTER 1: BACKGROUND

1.1. Introduction

This thesis explores how qualitative research approaches can help to identify treatment outcomes that are important to patients and how different qualitative data collection methods can inform the development of core outcome sets (COS) for use in effectiveness trials. This chapter provides background information on clinical trials, the development of COS and outlines the rationale for this research.

1.2. Clinical trials

Clinical trials allow us to evaluate the effects of interventions on patient outcomes in the population of interest. These data can provide valuable information to inform future patient care, pharmaceutical labelling claims, clinical guideline development and health policy (1, 2). The recognised gold standard for assessing healthcare interventions are randomised controlled trials (RCTs) (3-5). The observed effects in an RCT are due to the play of chance or the treatment allocation (6, 7). An RCT provides an unbiased estimate of the efficacy (the expected result of an intervention or treatment in ideal conditions) or the effectiveness (the benefit of a treatment or intervention in a real clinical setting) compared to the control arm. Trials also allow the assessment of adverse effects, which may be expected or unexpected, such as drug reactions however, it is possible that some rare or long-term adverse effects in the wider population may not be captured until after the treatment is licensed (8).

Clinical trials can be either explanatory or pragmatic (9-11). Explanatory trials measure efficacy (10). Participants in these trials tend to be homogenous, the results, therefore, may not be generalizable to the wider population (12). Pragmatic trials measure effectiveness, these trials recruit a heterogeneous group of participants in an attempt to reflect the wider population (11, 12). Nevertheless, it can still be difficult to assess the results of a clinical trial in the real world and there is a need for the design and conduct of “real world” effectiveness trials to address this issue (9, 13, 14).

Evidence from clinical trials should be transparent and reliable in order for key stakeholders to make informed decisions on the best care and treatment options for patients (15-17). If robust evidence is unavailable, treatments and interventions may prove to be harmful to patients (18) or may result in a waste of NHS resources and funding (19). In 2009, Chalmers and Glasziou reported that 85% of research investment is wasted and identified a number of things that can contribute to research waste (20). These include, the failure of researchers to look at what is currently known about their research area in order to identify gaps in existing knowledge (15), the under-reporting of outcomes (20) and researchers choosing to research what is interesting to them rather than what is important to patients (15). Ioannadis reported that poor research planning and design and the desire to report positive results in high impact journals for career progression can lead to waste (21). All of these scenarios can contribute to

unreliable evidence, making it difficult for those making decisions about which treatments or interventions are beneficial to patients.

1.3. Outcome selection in Trials

If the findings of a trial are to be valid, and applicable to a wider population, the selection of appropriate outcome measures in clinical trials is important (22). Outcomes can capture treatment effects, be used for evidence synthesis such as systematic reviews or meta-analysis or be used in prognostic modelling (23). Usually, clinical trials will collect data on a number of outcomes of interest but an inappropriately selected outcome measure may miss important information about the treatment and distort the findings (22, 24).

1.3.1. Types of outcomes routinely collected in trials

1.3.1.1. Primary outcomes

A primary outcome (also known as a primary endpoint or primary variable) should be the measure of perceived greatest benefit from the treatment, and in general, there should only be one primary outcome (25). If the outcomes are considered by the researchers to be of equal therapeutic importance they can select more than one primary outcome (26), however, due to multiple statistical testing and difficulties in interpreting the clinical benefit of the treatment, this is not generally recommended (26, 27). Some of the common types of outcomes

included in clinical trials are: mortality, major morbidity (such as hospitalisation), quality of life and health economics, depending on the nature of the research questions (25).

1.3.1.2. Secondary outcomes

Secondary outcomes (also known as secondary endpoints, secondary variables) are supportive measures related to the primary outcome (26, 28). They must be limited and related to the number of questions to be answered in the trial (25).

1.3.1.3. Surrogate outcomes

If a direct measurement of effect is not feasible or practical then an indirect measurement (a surrogate outcome) may be appropriate (25). An example of a surrogate outcome might be measures of blood pressure and/or cholesterol levels as a proxy measure for reduced mortality. It is important, however, that the surrogate measures are reliable predictors of clinical benefit. The disadvantage of surrogate outcomes is that favourable treatment effects seen in the surrogate outcome may not translate into health benefits for the patient (25, 27, 29).

1.3.1.4. Composite outcomes

Where multiple measurements are relevant to an outcome, it may be appropriate to integrate or combine them into a single or composite outcome (25, 30, 31). Composite outcomes address the issue of multiplicity without adjusting for type 1 error (to infer the existence of something that is not there) (25). For example, researchers may combine multiple clinical measurements (ratings scales) used in the medical area being researched, all-cause mortality and major morbidity (31, 32). By achieving just one of the component parts, a participant has achieved the composite outcome (30, 31, 33). However, unless researchers carefully report and discuss each of the composite outcomes individually in their publications readers may assume the effect applies to all of the composite outcomes which may not be the case (30).

1.3.1.5. Patient reported outcomes

A patient-reported outcome (PRO) is a report on the status of a patient's health condition received directly from the patient without amendment or interpretation by a clinician or anyone else (34). Patient reported outcomes measure aspects of patients' health such as; quality of life, anxiety, depression, fatigue, alcohol intake and diet (35, 36). When using appropriate PRO instruments in clinical trials, they can provide important information for researchers, policymakers and health authorities on patients' perspectives (37, 38).

1.3.1.6. Reporting of outcomes

Transparent reporting of all pre-specified outcomes at the end of a trial is essential to ensure that results are available for use by key stakeholders (clinicians, patients, carers, funding bodies, regulatory authorities, and policy makers) (3, 39). However, clear and transparent reporting does not always happen. Furthermore, even when results are reported they may not be relevant to, and meet the needs of, all stakeholders. The next section details some of the challenges created by the poor reporting of outcomes.

1.3.2. Current challenges with outcome assessment in trials

1.3.2.1. Outcome selection

The selection of outcomes in clinical trials is often inconsistent. For example, a review of oncology trials found that over 250,000 outcomes were reported just once or twice between 2007 and 2010 (40). Due to the heterogeneity of reported outcomes, synthesis of evidence may be difficult, limiting the number of comparisons. Therefore, it may be difficult to make a judgement on the effects of the treatment and subsequently make it hard for policymakers and funders to know where best to target funding and/or change clinical practice (16, 41-43).

1.3.2.2. Changes to outcomes during the study

Pre-specification of outcomes for a clinical trial is good practice, and generally no changes to outcomes should be made (44). However, occasionally changes to the selected outcomes can happen during a trial (44-47). Changes to outcomes can occur because of newly published results from other trials or as the result of the identification of better biomarkers. The reporting of any changes to outcomes must be clear, transparent and justified (44, 47). Changes to outcomes that are not justified or not reported clearly can compromise the scientific and ethical rigour of the trial. For example, sample size is based on the original primary outcome so the power of the trial may be affected, bias may be introduced and a type 1 error may occur (44). Prospective trial registration, pre-specification of outcomes in the study protocol, published protocols and adherence to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT), the Standard Protocol Items: Recommendations for Interventional Trials – Patient-Reported Outcomes (SPIRIT-PRO) and the Consolidated Standards of Reporting Trials (CONSORT statement) guidance can help to address this issue (3, 39, 44, 48).

1.3.2.3. Reporting bias

Reporting bias occurs when study personnel is selective in which outcomes they report in study findings, this can be due to the perception that only favourable findings are acceptable for publication (49-52). The prevention of reporting bias

is particularly relevant to COS (see section 1.4) and the aims of this thesis because if reporting bias can be addressed through the use of COS, evidence synthesis and comparisons will be easier thereby facilitating evidence-based decision-making (51, 53).

1.3.3. The relevance of outcomes to stakeholders

It is important that the outcomes selected for use in a clinical trial are relevant to all stakeholders including patients and policy makers, not just clinicians and academics (42). Evidence suggests that patients' views on which outcomes are most important to them differ to those which clinicians consider important (1, 54-56). Clinical and statistical considerations together with regulatory considerations have to-date guided the selection of outcomes in clinical trials which can result in the omission of outcomes important to patients (16, 57, 58). The approaches to selecting outcomes highlighted above are contrary to the aims and mission of the International Consortium for Health Outcomes Measurement (ICHOM) that states:

> *"Outcomes are the results people care about most when seeking treatment, including functional improvement and the ability to live normal, productive lives" (59).*

Outcomes that are important to patients are increasingly recognised and valued by policymakers (59, 60). Clinicians may choose to focus on outcomes that address mortality and morbidity but these do not provide them with information

about the impact of a health condition on patients (53, 61, 62). The effect of a health condition and/or treatment on patients' daily lives in terms of activities of daily living, mobility and their social life may be important. The information gained by measuring health related quality of life (HRQoL), for example, can help clinicians to better understand the impact of a health condition from the patients perspective and consequently talk to patients about their treatment options (63, 64). Facilitation of informed decision making around patients' care and treatment is possible if all clinical trials of the same health condition measure and report at least some of the same outcomes (53, 57, 65). To ensure that clinical trials collect data on the outcomes that matter to patients and that important outcomes are not omitted, patient participation in identifying those outcomes is important (65). If the outcomes measured in clinical trials are not patient focused, the result may be wasted research, ill-informed decisions around patient care leading to potentially harmful interventions and the waste of valuable healthcare resources (17, 53). See section 1.2 clinical trials for more information on research waste and section 1.3.1 for information on types of outcomes.

1.4. Core outcome sets

The use of COS may offer a solution to the problems associated with outcome selection and implementation in clinical trials (16, 66). A COS is a standardised set of outcomes to be reported and measured as a minimum in every trial in a specific health area (42). A COS is not restrictive and researchers can,

additionally, include outcomes that are relevant to their own research (67). The aim of a COS is to reduce the heterogeneity of outcome measurement and reporting in clinical trials of the same health condition (16, 53, 57). Standardisation of outcomes can help reduce reporting bias and facilitate evidence synthesis to inform clinical guidelines and health policy (16, 42, 57, 58, 68, 69).

1.4.1. Background to core outcome sets

As discussed earlier in this chapter, trial results may inform future patient care, health policy and clinical guidelines (19). It is therefore important that the selected outcomes are relevant to all stakeholders (42). Systematic reviews of evidence, if appropriately conducted, will produce more meaningful data if all studies in a particular health area report on the same set of core outcomes (69, 70).

One of the first research programmes around COS was the Outcome Measures for Rheumatology Clinical Trials (OMERACT). OMERACT was established in 1992 (71) with the aim of standardising outcomes and to promote the use of COS in rheumatology (72). Since then other groups have formed and are working to develop COS covering a number of different health areas such as evaluating maternity care (58), fibromyalgia (61), and eczema (73). In 2010, the Core Outcome Measures in effectiveness trials (COMET) initiative was launched

(57). The aim of the COMET initiative is to bring together those who are interested in the development, promotion, and reporting of COS (57). The specific objectives of the COMET initiative are (53):

1. To raise awareness of the problems with outcomes in clinical trials;
2. To encourage the development and uptake of COS;
3. To promote patient and public involvement in COS development;
4. To provide resources to facilitate the aims of the COMET initiative;
5. To avoid duplication of effort;
6. To encourage the development of evidence-based COS.

COMET provides an international searchable database of all studies relevant to COS development (74). The COMET database is updated on a continuous basis as eligible studies are identified additionally, individuals or groups can submit planned and ongoing studies for inclusion in the database.

In recent years, papers have reported that outcomes important to patients can vary to those outcomes healthcare professionals (HCPs) regard as important (75-77). For example, the OMERACT research programme found that the development of treatments to relieve fatigue was very important to rheumatoid arthritis patients whereas HCPs reported fatigue lower down on their list of priorities (75). This is consistent with Hewlett's 2003 review of the compatibility of patient and professional views on outcomes in arthritis (54). The findings suggest that outcomes identified by HCPs and researchers may not be regarded

as relevant to patients, thereby highlighting the value of eliciting outcomes that are important to patients as part of a COS development process (16, 53, 65, 66). Sanderson, aware of the potential for differences of opinion between patients and healthcare professionals regarding the importance of outcomes, developed a patient core set of outcomes to complement the clinician set of outcomes for rheumatoid arthritis patients with the aim of promoting the inclusion of patient outcome priorities (62, 78).

1.4.2. The process of developing a COS

Work to establish the best methods and processes to develop a COS is ongoing. The COMET handbook details the process of developing a COS (53); however, currently no consensus on the optimal method exists. In brief, the development process involves identifying that a COS is required and defining the scope of the COS; deciding which stakeholders (including patients and public) to involve and how to involve them; deciding what to measure; which data collection methods to use; developing a protocol; and registering the project on the COMET database. The COMET handbook (53) recommends using the first three elements of the PICO (Population, Intervention, and Comparator) tool to help with this exercise (79, 80). Once the scope has been defined the COS developers need to decide what to measure. Developers can identify a long list of potential outcomes from sources such as systematic reviews of existing outcomes collected in trials, and/or surveys, and/or qualitative work (53). The identified long list of outcomes is then typically taken forward into one or more prioritisation exercises such as

the nominal group technique, a Delphi exercise, a consensus meeting or a combination of these (16, 81-83). See Table 1.1 for a brief description of these methods.

Table 1.1 Prioritisation methods

Prioritisation method	Description
Consensus meeting	Group decision-making process, which may include anonymous voting. Members discuss, develop and agree on outcomes to be included in the final COS based on those that are in the best interest of the majority of stakeholders.
Delphi	In a Delphi, participants reply to questions in a number of rounds (generally 2-3). After each round participants receive generalised feedback on the responses of other participants. The process is repeated with the aim of reducing the range of responses and achieving consensus. Thresholds for taking items into subsequent rounds will be predefined.
Nominal group technique	In its basic form, a discussion about the outcomes and the process takes place followed by participants ranking each of the outcomes. The outcomes with the highest total scores are included in the COS.

To date, HCPs are the largest stakeholder group taking part in COS development (16, 81) and the most commonly used methods to identify and prioritise potential outcomes for inclusion in a COS are systematic reviews and the Delphi technique respectively (81, 84). However, if COS are to be relevant to all stakeholders there is a need for more patient and carer involvement in their

development (16). For maximum benefit to be gained from a COS, Young recommends that all stakeholders (clinicians, patients, carers, funding bodies, and decision makers) should reach consensus over which outcomes go into a COS (65). The final COS should be relevant to the intended population and the COS development process should be transparent (53).

1.4.3. The relevance of this research to core outcome set development

Although patient and carer involvement in COS development has increased over the last few years (16, 81) there is still scope for further improvement (65, 66). When patients and carers are involved, the most appropriate methods of identifying outcomes important to them are currently unknown (53). Outcomes identified from systematic reviews are typically weighted in favour of the views of clinicians and academics, this is because the decision on which outcomes to measure were most likely decided by the clinician and/or academic (16, 57, 58). Subsequently, there is a danger that the patient voice may get lost or not be included at all (16, 57, 58, 85). There is also evidence to suggest that when patients are asked about outcomes that are important to them using survey data collection methods there is a tendency for them to rate all items as important (86). This could in part be due to the concept of outcomes and what they mean can sometimes be difficult for patients to understand and articulate (87), or it may reflect the different responses elicited through asking closed and open questions (88, 89). Open questions provide an opportunity for participants to answer in their own words whereas a survey generally asks participants to select

answers from a predetermined list, which may not adequately reflect their feelings and experiences (88, 90, 91). This may explain why they feel they should rate most things as important. Identifying methods of accessing in-depth information about outcomes important to patients will help COS developers to understand the value patients place on them. Subsequently, users of trial evidence can be more confident that the final COS is relevant to all stakeholders. Qualitative data collection methods may be an appropriate way of capturing information about which outcomes patients regard as important and why they are important (88, 89, 92). Qualitative data can provide us with information on the vocabulary patients use when talking about their illness and the effect it has on their daily lives (53, 66, 82). Similar to the concept of outcomes, the prioritisation stages of a COS development process can be confusing for patients, especially if they do not understand the descriptions provided for each of the outcomes by the research team (53, 65). These descriptions may be more accessible by using patients' own words, extracted from relevant qualitative data (66, 87).

Core outcome sets are, in the main, designed to be applicable to all trials and therefore imply generalisability. Conversely, qualitative research is subjective in nature, is open to interpretation by the researcher, and does not claim to be generalisable. The extent to which the findings of qualitative research are transferable can depend on several things such as the time, the place, cultural context, the interpretation of the data, the inferences made from the data by the researchers and the clear and transparent reporting of the processes involved (89). Qualitative research methods do not provide estimates of the prevalence of

views related to certain issues, including outcomes nor are they prioritisation or consensus exercises. Therefore, qualitative methods have to-date been used within the COS development process as a precursor to prioritisation and consensus exercises rather than a standalone method. As part of these processes qualitative research findings can provide insight into why outcomes are important to patients and the language patients use when talking about their health condition. Additionally, using outcomes identified through qualitative research with patients may reduce the number of Delphi rounds required by removing the need for an open-ended round (53).

Gargon recommends that further research is undertaken to establish the best method(s) of eliciting patient views in the context of COS development (16). It is currently unclear which qualitative data collection methods for example, interviews and/or focus groups, will most usefully inform COS development. The nature of the data collected to inform COS development may differ depending on which qualitative method is used. Generally, interviews are likely to produce rich detail of one person's individual experience whereas focus groups generate group opinion and experiences through participant interaction (89, 93-95). New approaches to qualitative data collection should also be considered such as online focus groups or online forums which may be less resource intensive and may yield different data and allow access to different populations (96, 97). Although not developing a COS, Synnot's study comparing face-to-face focus groups with an online forum reported that the face-to-face groups generated discussion between the participants whereas the online forum generated

thoughtful reflection and description (98). The combination of interview and focus group data may help bring together a complete picture of the findings because each method is likely to reveal different aspects of the topic under investigation (99). Face-to-face interviews and focus groups are well-established methods for collecting in-depth qualitative data (88, 89). In an increasingly technical world, online focus groups, although relatively new, may provide an additional data collection method for qualitative researchers to consider. If online focus groups can produce in-depth data around outcomes this method may have the potential to become an effective and cost effective tool in the COS developers' tool kit.

In order to enhance the existing knowledge around qualitative data collection methods and COS development, the differences between different qualitative data collection methods need to be understood. To establish this we need to understand whether different types of qualitative data collection methods influence the outcomes generated for prioritisation exercises, the richness of the data and the underpinning evidence in support of outcome selection. In addition, the strengths, weaknesses and resource use associated with each data collection method should be assessed.

To-date comparisons of qualitative data collection methods have not considered the identification of outcomes for clinical research purposes or the use of qualitative research in COS development. A comparison of face-to-face and online focus groups with a focus on COS development specifically comparing the

range of outcomes elicited, the depth of the data and the resources required will help inform future COS development. The development of a COS is often time and resource limited so understanding the differences between qualitative data collection methods and the potential trade-offs is especially important.

1.5. A case study of burns injury

The NHS burns service treats 2845 burn injured patients each year, although a large proportion of these will not require admittance to a specialist burns unit (100). For those who require admission to a specialist burns unit advances in medicine mean that patients are increasingly surviving their injuries (101-103). A burn injury can affect patients' physical and psychological well-being and recovery and rehabilitation can be a long process. Therefore, consideration of treatment outcomes other than survival is pertinent. Obtaining patients' perspectives on defining what outcomes should be assessed/measured is key to ensuring treatments are appropriate to patients' needs (104). The development of a COS for burns injuries with the input of all stakeholders will ensure the consistent measurement and assessment of the identified outcomes in all clinical trials of burns interventions. The consistent measurement of a standard set of outcomes will provide reliable evidence enabling informed decision making around the best treatments for burns patients. The PEGASUS feasibility study (105, 106) (see Box 1.1) provided an ideal case study to build upon and to compliment my own primary research on which outcomes are important to burns patients. This study had already completed primary data collection using

interviews as part of an NIHR funded study (project number 12/145/04) which could be directly compared with face-to-face and online focus group data; the primary data collected for this research.

The PEGASUS feasibility study (see Box 1.1) elicited views from both adult patients with burns and parents and carers of children with burns. The OSCAR study, this primary research, was limited to adult burns patients (aged ≥16 years) who had experienced a burn injury and had experienced scar management therapy and hence only this component of the PEGASUS feasibility study is summarised in Box 1.1.

Case study of the PEGASUS Feasibility Study

(ethical approval: 14/WM/0160)

Overarching Aim

To evaluate the feasibility of running a randomised controlled trial to assess the effectiveness and cost-effectiveness of pressure garment therapy

Qualitative component of the trial (one to one interviews with adult burns patients)

Aims - to elicit views on:

- Experiences of burn injury and pressure garment therapy
- Views on a randomised controlled trial
- Outcome preferences
- Appropriate assessment time-points

Sampling

Purposive maximum variation sampling according to:

- Age
- Sex
- Ethnicity
- Skin colour
- Type of burn (e.g. flame, chemical)
- Severity of burn
- Time since injury
- Completion of PGT

Inclusion criteria

- Adults aged ≥16 years
- Good spoken English
- Patients who have received pressure garment therapy for at least 6 months
- Patients may have completed pressure garment therapy, but no longer than two years ago

Exclusion criterion

- Patients who have received pressure garment therapy for conditions other than burns

Box 1.1 PEGASUS feasibility study

1.6. Aims and objectives of the thesis

1.6.1. Aims

1. To build knowledge of how qualitative research with patients can effectively inform the development of COS that resonate with the range of users of trial-derived evidence;
2. To compare the use and utility of three qualitative data collection methods for understanding which outcomes are most important to patients and why.

1.6.2. Objectives

1. To review critically the methods used to develop COS with a particular emphasis on the participation of patients and carers and qualitative methods;
2. To review critically the existing research that has compared the use and utility of novel online qualitative data collection methods (focus groups) available to COS developers, with more traditional face-to-face approaches;
3. To compare the outcomes that are important to patients elicited through three different qualitative data collection methods (interview, face-to-face focus groups, online focus groups), and to provide

insights into any differences and similarities between the methods. Specifically, the range of outcomes elicited the depth of the data around the outcomes and the characteristics and diversity of the sample;

4. To document and report the related resource use (i.e. time and cost) and the strengths and limitations associated with each approach;
5. To conduct primary research using face-to-face and online focus group data collection methods to establish patient outcome priorities and to re-analyse patient interview data collected as part of the PEGASUS feasibility study in order to achieve objectives 3 and 4.

1.7. Overview of chapters

Chapter 2 is a review of the COS development papers held on the COMET database. The aim was to identify and describe how patients and carers have been included as participants in COS development exercises with a particular focus on those using qualitative data collection methods and the reporting of those methods.

Chapter 3 is a narrative review of papers comparing data collected by face-to-face and online focus groups methods. The findings helped to inform the development of the primary research.

Chapter 4 provides detail and justification of the methodology and methods chosen for the primary data collection and analysis and the re-analysis of the PEGASUS feasibility study interviews.

Chapter 5 reports the results of the primary research (the OSCAR study) and the re-analysis of the PEGASUS study interviews. Comparison of the datasets established the similarities and differences in the data collected by each of the methods used.

Chapter 6 discusses the findings of this work in relation to the aims of the research and the current literature. The discussion includes reflections on the methodological strengths and weaknesses, how it adds to the existing knowledge on COS development, the implications of the findings, and recommendations for future research.

1.8. Summary

This chapter provides the background for the research reported in this thesis. It has discussed the use of outcomes in clinical trials and the existing problems associated with them. The chapter then explained how COS aim to address the problems associated with outcomes and the importance of involving patients in the development of COS to ensure their relevance to all stakeholders.

CHAPTER 2: A REVIEW OF PATIENT AND CARER PARTICIPATION AND THE USE OF QUALITATIVE RESEARCH IN THE DEVELOPMENT OF CORE OUTCOME SETS

2.1. Introduction

This chapter is presented in paper format.

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RESEARCH ARTICLE

A review of patient and carer participation and the use of qualitative research in the development of core outcome sets

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Abstract

Background

To be meaningful, a core outcome set (COS) should be relevant to all stakeholders including patients and carers. This review aimed to explore the methods by which patients and carers have been included as participants in COS development exercises and, in particular, the use and reporting of qualitative methods.

Methods

In August 2015, a search of the Core Outcomes Measures in Effectiveness Trials (COMET) database was undertaken to identify papers involving patients and carers in COS development. Data were extracted to identify the data collection methods used in COS development, the number of health professionals, patients and carers participating in these, and the reported details of qualitative research undertaken.

Results

Fifty-nine papers reporting patient and carer participation were included in the review, ten of which reported using qualitative methods. Although patients and carers participated in outcome elicitation for inclusion in COS processes, health professionals tended to dominate the prioritisation exercises. Of the ten qualitative papers, only three were reported as a clear pre-designed part of a COS process. Qualitative data were collected using interviews, focus groups or a combination of these. None of the qualitative papers reported an underpinning methodological framework and details regarding data saturation, reflexivity and resource use associated with data collection were often poorly reported. Five papers reported difficulty in achieving a diverse sample of participants and two reported that a large and varied range of outcomes were often identified by participants making subsequent rating and ranking difficult.

patents, products in development, or marketed products to declare relating to this publication. This does not alter the authors' adherence to all PLOS ONE policies on sharing data and materials.

Conclusions

Consideration of the best way to include patients and carers throughout the COS development process is needed. Additionally, further work is required to assess the potential role of qualitative methods in COS, to explore the knowledge produced by different qualitative data collection methods, and to evaluate the time and resources required to incorporate qualitative methods into COS development.

Introduction

Clinical trials in health care provide important evidence of the efficacy and safety of interventions and treatments [1], thereby informing future patient care, clinical guidelines and health policy [2, 3]. The selection of outcomes to be measured and reported is an important part of the trial design process. Historically, the selection of outcomes has usually been based on the views of individual study teams informed by clinical and statistical considerations, and guided by regulatory considerations [4–6]. This is problematic since outcomes that matter to key stakeholders, including patients and carers, may be omitted. Furthermore, a wide variety of outcomes may be measured and reported across trials in the same health area "making it difficult or impossible to synthesise the results of different studies" [6] (p1). The difference in outcomes used across studies can also make it hard to detect reporting bias, where authors fail to report all findings because of the desire to report only positive results [7]. Greater uniformity in the reporting of outcomes and measures within a research area would help to facilitate the comparison and synthesis of research findings [7, 8].

One potential solution to this problem is the use of core outcome sets (COS). A COS is an agreed standardised set of outcomes to be measured and reported as a minimum in all trials in a specific health related area [6]. If implemented, a COS may help to ensure that outcomes are relevant to a range of stakeholders and will provide consistent trial outcome data to inform evidence synthesis, clinical practice, shared-decision making and health policy [9, 10]. Stakeholders can include patients, carers, patient representatives and patient advocates (reported as patients and carers from this point onwards), as well as healthcare professionals and decision makers including: funders, researchers, statisticians, health economists and pharmaceutical company representatives (reported as health professionals from this point onwards) [4, 10]. Ultimately, it is the patients and those around them (carers) who benefit from improved healthcare and so it is important that their views and preferences are heard, particularly as there is evidence to suggest that patients' perspectives may differ from those of clinicians [11].

Despite the potential benefits of including a wide range of stakeholders in COS development, evidence to-date demonstrates that relatively few (18%) COS exercises include patients and carers and the reporting of the process does not always make it clear how they have participated [6]. Gargon et al. [6] recommended that further work is carried out to identify effective methods of eliciting patient and carer views in outcome set development. Data generated using qualitative methods can help to provide in-depth insight into patients' and carers' perspectives [12]. Therefore, qualitative methods could be well placed to identify outcomes that are important to patients and carers and to understand why that is. The aim of this review was therefore to: 1) review the methods by which patients and carers have been included as participants in COS development and 2) explore and describe the reported use of qualitative research with patients and carers. For the purpose of this review we were interested in participation, that is where patients and carers contribute data to COS development exercises as research

participants, rather than involvement, where they contribute to the research process as an active research partner or advisor.

Methods

Data source

The Core Outcome Measures in Effectiveness Trials (COMET) Initiative "aims to bring together people interested in the development, reporting and promotion of COS, derived using rigorous consensus methods" [4]. The COMET Initiative database is an international repository of studies relevant to the development of COS, planned, ongoing and completed [13]. The COMET database was developed based on a systematic review using extensive searches [4] and the COMET Initiative conduct an annual search of the literature in order to keep the database up to date [13]. In addition, planned and ongoing COS exercises can be submitted to COMET by individuals or groups for inclusion in the database [13].

Search strategy

Given that the COMET database is a comprehensive source for COS development studies with the contents regularly updated, we limited our search to this one database.

COS Studies involving patient/carer involvement. The COMET database was searched on the 13 August 2015 using the following search categories: Carer organisations / Support group representatives, Charities, Conference participants, Consumers (caregivers), Consumers (patients), Families, Individuals with a known interest, Patient / Support group representatives, Service users, Guideline developers, with a study type of COS. Inclusion criteria were: papers developing COS with patients and carers as research participants. In addition, reference searches of the included papers were conducted.

Qualitative studies to inform COS development involving patients and carers. From these searches we identified all papers that described research using qualitative data collection methods (e.g. focus groups, interviews).

Data extraction and reporting

A data extraction pro-forma was developed, piloted and used to record study specific information: title, author, year, location of study (country), health area and data collection dates. For COS papers not using qualitative data collection methods we extracted the data collection methods used and the number of health professionals and patient and carer representatives participating in these. For papers reporting qualitative data collection methods we extracted; the stated qualitative methodological framework and rationale for this (please note: in qualitative research the methodological framework guiding research conduct, such as grounded theory, phenomenology or ethnography is distinguished from the methods used during conduct e.g. sampling, data collection, analytic approach) [14]; methods (sampling approach; data collection and analysis); sample characteristics; resource use (costs, resources and time involved); stated strengths and limitations and stated impact of the qualitative research). Some data items were informed by the CASP Qualitative Checklist [15].

The lead author (JJ) extracted data from all included papers and a second researcher (JMM, LLJ, MJC or TJHK) checked the extraction for accuracy on all papers reporting the use of qualitative methods. Any discrepancies were resolved via discussion within the research team. Data extraction were combined when a COS development exercise was reported across more than one paper. Data have been summarised descriptively. Recommendations have been made for the transparent reporting of qualitative research to inform COS development.

Results

COS studies with patients and carers

Included papers. Of the 666 records on the COMET database, our initial search strategy returned 149 papers (Fig 1). Seventy-three of the returned studies were unpublished, and of the remaining 76, 24 were excluded because there were insufficient details to determine whether they were reporting a COS including patients or carers. Through reference searches of the included papers an additional seven papers [16–22] were identified as part of the included COS development exercises. Of these, four [16, 19, 21, 22] were not archived on COMET at the point of the final search and three [17, 18, 20] papers were not returned in the initial search because they did not include patients or carers as participants; however, they described part of a COS pathway which included patient or carers reported in a separate publication.

Participants in the COS development. The 59 included papers represent a total of 34 COS development exercises covering 32 different health areas (Table 1). In 19 papers the number of participants was unclear.

The data collection methods used in COS development including patients and carers were; Delphi exercises (n = 14), consensus conferences/meetings (n = 20), surveys (n = 10), interviews (n = 6), focus groups (n = 6), nominal group techniques (n = 9) and other (n = 5). For the methods where participant numbers were reported fully, the mean percentage of patients and carers in each ranged from 20% to 86% (Table 2). Patients and carers formed the majority or all of the participants in surveys, interviews and focus groups. Health Professionals formed the majority of participants in nominal group techniques, Delphi exercises and consensus meetings. In all cases where qualitative data collection methods were utilised the primary aim was to identify outcomes of importance to the participants.

Qualitative studies to inform COS development involving patients and carers

Ten papers [16, 19, 21, 22, 24, 30, 32, 34, 35, 37] reported using qualitative data collection methods to identify outcomes important to patients and carers (Table 3). However, of these only three were clearly reported as part of a COS development process [16, 24, 30]; five discussed outcomes with patients and carers but it was unclear whether the data were collected specifically with the intention to include them in a COS [21, 32, 34, 35, 37]; and two further studies were conducted for other primary research aims, such as exploring perceptions of access to care [19, 22].

Methodological framework. Of the papers reporting a qualitative approach in the development of a COS [16, 19, 21, 22, 24, 30, 32, 34, 35, 37] none explicitly reported an underpinning methodological framework.

Sampling. Eight papers [16, 19, 21, 22, 24, 30, 34, 35] reported using purposive sampling and two [32, 37] did not discuss a clear sampling strategy. All papers gave details of participant age, gender and some clinical detail (e.g. disease severity). However, some omitted details on socio economic status [19, 21, 22, 24, 30, 32, 34, 35] and ethnicity [19, 21, 22, 30, 34, 35]. Nine papers [16, 19, 22, 24, 30, 32, 34, 35, 37] recruited participants from a single country but one paper [21] included participants from five different European countries.

Data collection. Four papers reported interviews with patients and carers as the only data collection method [19, 30, 34, 35]. The number of interviews reported in these studies ranged from 22 to 31. Focus groups were the only method reported in four papers: Arnold [24] and Saketkoo [32] conducted six focus groups, Turk [37] four, and Stamm [21] ten. There was an

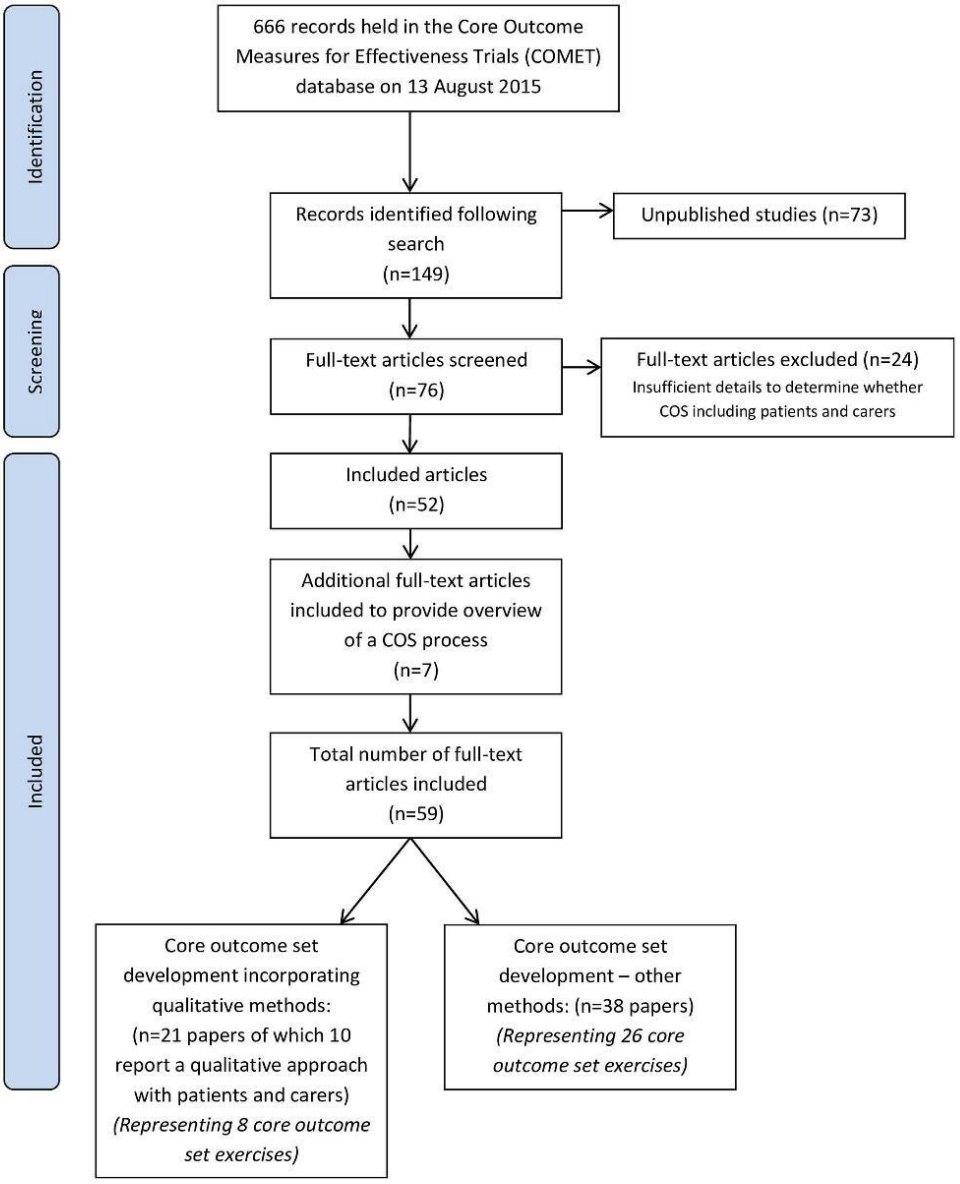

Fig 1. Flow diagram of paper identification and inclusion process.

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Table 1. Summary of included papers.

Reference	Publication year	Health area	Ethics committee approval obtained	Data collection methods	Health Professionals (n)	Patients (n)	Carers and/or representatives (n)
Core outcome set development exercises using qualitative methods with patients, carers and representatives							
Allard et al [16][α]	2014	Neurodisability	Not stated	Focus groups	0	50	47
				Interviews	0	4	6
Janssens [17] et al[α]	2014	Neurodisability	Not stated	Delphi	233	0	0
Morris et al [23] et al	2015	Neurodisability	Not stated	Other[Ω]	7	3	5
Arnold et al [24]	2008	Fibromyalgia	Yes	Focus groups	0	48	0
Mease et al [25]	2008	Fibromyalgia	Yes	Delphi	23	100	0
Mease et al [26]	2007	Fibromyalgia	Yes	Consensus meeting	Not stated	Not stated	0
Mease et al [27]	2009	Fibromyalgia	Not stated	Consensus conference	Not stated	Not stated	0
Stamm et al [21][α]	2009	Osteoarthritis	Yes	Focus groups	0	56	0
Kloppenburg et al [28]	2014	Osteoarthritis	Not stated	Delphi	31	0	0
				Other[Ω]	Not stated	Not stated	0
Potter et al [19][αππ]	*2013*	*Breast cancer*	*Yes*	*Interviews*	*35*	*31*	*0*
Potter et a [20][α]	*2014*	*Breast cancer*	*Yes*	*Interviews*	*35*	*0*	*0*
Potter et al [29]	2015	Breast cancer	Yes	Delphi	88	215	0
				Consensus meeting	23	15	0
Sanderson et al [30]	2010a	Rheumatoid arthritis	Yes	Interviews	0	23	0
Sanderson et al [31]	2010b	Rheumatoid arthritis	Yes	Nominal group technique	0	26	0
				Survey	0	254	0
Swigris et al [22][α]	*2005*	*Interstitial lung disease (IPF)*	*Yes*	*Interviews*	*0*	*5*	*0*
				Focus groups	*0*	*15*	*0*
Saketkoo et al [32]	2014a	Interstitial lung disease (CTD)	Yes	Focus groups	0	45	0
				Delphi	254	0	0
Saketkoo et al [33]	2014b	Interstitial lung disease (CTD)	Yes	Nominal group technique	23	5	0
Tierney et al [34]	2013	Cleft palate, otitis media	Yes	Interviews	0	0	43
Tierney et al [35][¥]	2015	Cleft palate, otitis media	Yes	Interviews	0	22	43[π]
Harman et al [36]	2015	Cleft palate, otitis media	Yes	Survey	0	8	35
				Delphi	104	0	0
				Consensus meeting	11	0	5
				Follow-up workshop	1	0	9
Turk et al [37]	2008	Chronic pain	Yes	Focus groups	0	31	0
				Survey	0	959	0
Core outcome set development exercises using other methods							
Bellm et al [38]	2002	Oral mucositis	Not stated	Other[Ω]	9	2	0
Bennett et al [39]	2012	Gestational diabetes mellitus	Not stated	Survey	4	0	2
				Consensus meeting	4	0	2
				Delphi	7	0	2
				Online evaluation	Not stated	0	Not stated
Broder et al [40]	2000	Uterine fibroids	Not stated	Delphi	9	0	1
				Nominal group technique	10	0	1
Buch et al [41]	2015	Rheumatic diseases	Not stated	Other[Ω]	20	2	0
				Delphi	20	1	0

(*Continued*)

Table 1. (*Continued*)

Reference	Publication year	Health area	Ethics committee approval obtained	Data collection methods	Health Professionals (n)	Patients (n)	Carers and/or representatives (n)
Carlson et al [42]	2003	Mania/Bipolar disorder	Not stated	Consensus conference	53	0	Not stated
Chiarotto et al [43]	2015	Lower back pain	Exempt	Delphi	129	14	0
Chitnis et al [44]	2012	Multiple Sclerosis	Not stated	Survey	51	0	Not stated
Chitnis et al [45]	2013	Multiple Sclerosis	Not stated	Consensus meeting	69	0	Not stated
				Survey	Not stated	0	0
Devane et al [5]	2007	Maternity care	Yes	Delphi	194	9	15
Gladman et al [46]	2005	Psoriatic arthritis	Not stated	Nominal group technique	Not stated	Not stated	0
Gladman et al [47]	2007	Psoriatic arthritis	Not stated	Consensus meeting	Not stated*	Not stated*	0
Goldhahn et al [48]	2014	Distal radius fracture	Not stated	Nominal group technique	Not stated[0]	Not stated[0]	0
Gonzalez et al [49]	2011	Vitiligo	Not stated	Consensus meeting	Not stated	Not stated	0
Eleftheriadou et al [50]	2012	Vitiligo	Yes	Survey	Not stated	Not stated[Ψ]	0
Eleftheriadou et al [51]	2015	Vitiligo	Not stated	Delphi	69	32	0
Haeusler et al [52]	2015	Febrile neutropenia	Not stated	Delphi	39	4	0
Haywood et al [53]	2014	Hip fracture	Not stated	Survey	13	1	3
				Nominal group technique	22	0	3
Karas [54]	2015	Acute diarrhoea	Not stated	Delphi	70	0	31
Katona et al [55]	2007	Dementia	Not stated	Consensus conference	33	0	3
Merkies et al [56]	2006	Peripheral neuropathy	Not stated	Consensus conference	22	1	0
Moniz-Cook et al [57]	2008	Dementia care	Not stated	Consensus meeting	Not stated	0	0
				Survey	131	0	5
				Consensus meeting	Not stated	0	0
				Consensus meeting	Not stated	0	0
Reilly et al [58]	2006	Charcot-Marie-Tooth disease type 1A	Not stated	Consensus conference	21	2	0
Salaffi et al [59]	2012	Fibromyalgia	Yes	Delphi	252	86	0
Schmitt et al [60]	2007	Eczema	Not stated	Survey	6	4	2
Schmitt et al [61]	2010	Eczema	Not stated	Consensus conference	Not stated[#]	Not stated[#]	Not stated[#]
Schmitt et al [62]	2011	Eczema	Not stated	Delphi	40	6	0
Schmitt et al [63]	2012	Eczema	Not stated	Nominal group technique	38	5	0
Sinha et al [64]	2012	Asthma	Yes	Delphi	46	0	0
				Survey	0	11	88
Stuart et al [65]	2011	Ovarian cancer	Not stated	Consensus conference	Not stated	0	Not stated
Thigpen et al [66]	2011	Ovarian cancer	Not stated	Consensus conference	Not stated	0	Not stated
Tugwell et al [67]	1993	Rheumatoid arthritis	Not stated	Consensus conference	Not stated	Not stated	Not stated
				Nominal group technique	Not stated	Not stated	Not stated

(*Continued*)

Table 1. (*Continued*)

Reference	Publication year	Health area	Ethics committee approval obtained	Data collection methods	Health Professionals (n)	Patients (n)	Carers and/or representatives (n)
Kirwan et al [68]	2003	Rheumatoid arthritis	Not stated	Consensus conference	46	11	0
Kirwan et al [69]	2005	Rheumatoid arthritis	Not stated	Consensus conference	160	19	0
Kirwan et al [70]	2007	Rheumatoid arthritis	Not stated	Consensus conference	60	20	0
Van der Heijde et al [71]	1997	Ankylosing spondylitis	Not stated	Other$^{\Omega}$	Not stated	Not stated	0
				Nominal group technique	Not stated	Not stated	0
Vargus-Adams et al [72]	2009	Cerebral palsy	Yes	Delphi	39	21	23
MacKichen et al [18]$^{\alpha}$	2015	Chronic pain after total knee replacement	Not stated	Focus groups	18	0	0
Wylde et el [73]	2015	Chronic pain after total knee replacement	Yes	Delphi	39	71	0
				Consensus meeting	Not stated	12	0

*total number of participants = 137, breakdown not provided.

^{0} total number of participants = 26, breakdown not provided.

$^{\#}$total number of participants = 40, breakdown not provided.

$^{\Psi}$ total number of participants = 461, breakdown not provided.

$^{\alpha}$ Papers not in original search, included because they are part of the COS pathway.

$^{¥}$ Full details given in Tierney 2013.

$^{\Omega}$ Other = meetings/semi-structured discussions.

Papers in italics have a qualitative component which was carried out prior to the COS exercise and was not specifically designed for the COS work but has fed into it.

Not Stated = participants in stakeholder group implied by numbers not given.

N.B. Papers grouped together are part of the same COS exercise.

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average of seven participants per group. A combination of interviews and focus groups were reported in two papers; Allard [16] who carried out ten individual interviews and 12 focus groups (97 participants) and Swigris [22] who conducted five individual interviews and three focus groups (15 participants).

All studies were audio-recorded and transcribed verbatim, and all reported using topic or discussion guides. However, only four [16, 19, 30, 34] provided details of the contents or derivation of these.

Table 2. Mean percentage of Health professionals to patients and carers by data collection method.

Method	Health Professionals (mean %)	Patients and carers (mean %)
Consensus meetings/conferences (n = 9)	80	20
Delphi (n = 19)	77	23
Nominal group technique (n = 5)	70	30
Surveys (n = 8)	36	64
Interviews (n = 7)	22	78
Focus groups (n = 7)	14	86

N.B. not all papers provided a full breakdown of participants and are therefore not included.

https://doi.org/10.1371/journal.pone.0172937.t002

Table 3. Reporting of qualitative methods with patients and carers.

	Allard 2014 [16]	Arnold 2008 [24]	Potter 2013 [19]	Saketkoo 2014a [32]	Swigris 2005 [22]	Stamm 2009 [21]	Sanderson 2010a [30]	Tierney 2013 [34]	Tierney 2015 [35]	Turk 2008 [37]
Health area	Neurodisability	Fibromyalgia	Breast cancer	Interstitial lung disease	Interstitial lung disease	Osteoarthritis	Rheumatoid arthritis	Cleft palate, otitis media	Cleft palate, otitis media	Chronic pain
Theoretical framework	N/R	N/R	N/R	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Sampling										
Approach	Purposive	Purposive	Purposive	N/R[#]	Purposive	Purposive	Purposive	Purposive	Purposive	N/R[#]
No. approached	N/R	N/R	N/R	N/R	N/R	N/R	N/R	N/R	N/R	N/R
No. taking part	107	48	31	45	20	56	23	43	22	31
Age	Yes	Yes	Yes	Yes[Ψ]	Yes	Yes	Yes	Yes	Yes	Yes
Gender	Yes	Yes	Yes	Yes[Ψ]	Yes	Yes	Yes	Yes	Yes	Yes
Ethnicity	Yes	Yes	N/R	Yes[Ψ]	N/R	N/R	N/R	N/R	N/R	Yes
Socio economic status	Yes	N/R	N/R	N/R	N/R	N/R	N/R	N/R	N/R	Yes
Clinically relevant info	Yes	Yes	Yes	Yes[Ψ]	Yes	Yes	Yes	Yes	Yes	Yes
Data collection										
Focus groups	Yes	Yes	n/a	Yes	Yes	Yes	n/a	n/a	n/a	Yes
Interviews	Yes	n/a	Yes	n/a	Yes	n/a	Yes	Yes	Yes	n/a
Data analysis										
A priori categories applied	Yes (plus emergent themes)	No	No	No	No	No	No	No	No	No
*Thematic/ content analysis**	Yes	n/a	n/a	Yes	Yes	Yes	n/a	Yes	Yes	Yes
*Grounded theory***	No	Yes	Yes	No	No	No	Yes	No	No	No
*Framework approach****	Yes	No	No	No	No	No	Yes	Yes	Yes	No
Data saturation mentioned	Yes	No	Yes	No	Yes	No	Yes	No	No	No
Triangulation										
Multiple coders/ perspectives	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Data collection methods (both focus groups and interviews)	Yes	No	No	No	Yes	No	No	No	Yes	No
Reflexivity	No	Yes	Yes	No	No	No	No	No	No	No

N/R = not reported, n/a = not applicable,

[#] = Some indication of types of participant included but not the sampling approach used.

[Ψ] Details reported in Saketkoo 2014b.

* Paper describes a generic thematic / content approach

** Paper describes analysis informed by Grounded Theory approaches, rather than an explicit Grounded Theory methodological framework

*** Paper refers to the use of framework as part of the analytical process

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Data analysis. Only one of the papers [16] reported the use of a priori categories in the analysis, with most using exclusively inductive data-driven approaches. Seven papers [16, 21, 22, 32, 34, 35, 37] reported using thematic or content analysis. Arnold [24], Potter [19] and Sanderson [30] reported analysis based upon the principles of grounded theory. Four papers also referred to the use of the framework approach in the analytical description [16, 30, 34, 35].

Four interview studies reported reaching data saturation [16, 19, 22, 30]. In two cases, saturation was judged in conjunction with focus group data [16, 22]. None of the papers reporting on focus groups only [21, 24, 32, 37] described achieving data saturation.

Triangulation. Data were analysed using multiple coders of and/or perspectives on the data in all of the included papers. Three [16, 22, 35] reported on the triangulation [74] of two different data collection methods (interviews and focus groups).

Reflexivity. Only two papers [19, 24] included any reflexive content. Potter [19] reported the use of a medically trained interviewer and reflected on the influence this may have had on the results. Arnold [24] discussed the use of an experienced facilitator with no prior knowledge of the condition under investigation, to avoid leading discussions.

Reported strengths and limitations. All studies acknowledged some strengths and limitations of their work. The main limitation noted in the included papers concerned recruitment. Five papers reported on the difficulty in recruiting an ethnically diverse and gender balanced sample [16, 24, 30, 33, 34]. Four discussed that they were unable to recruit participants to fulfil the desired sampling quota, for example, with not all categories of the disease/investigation under investigation being included [16, 24, 30, 37].

Sanderson [31] and Turk [37] reported that patients and carers identified a rather large and varied range of outcomes important to them, making subsequent rating and ranking very difficult. Potter [19] and Tierney [34] also highlighted the difficulty that participants may have when asked to recall their treatments and experience.

The participation of patients and carers in the core outcome set process was identified as a strength in 3 papers. Allard [16] stated that the differences between patients and parents were highlighted, and Sanderson [30] and Saketkoo [32] both reported that outcomes identified by patients and carers as important to them were not in current professional core outcome sets.

Resource use associated with qualitative methodology. Other than details on the length of the focus groups and interviews and reimbursements, very little information about the resources required to carry out qualitative data collection methods in COS development was reported in the included papers.

Planned and ongoing studies. As of 13 August 2015, 73 studies (S1 appendix) were registered on the COMET database as planned or ongoing COS development studies. Of these, all studies reported that they intended to include patients and carers as participants and 37 (52%) stated they wouldbe using qualitative methods as part of the COS pathway (S2 appendix). Of these 37, 21 planned to use both interviews and focus groups. Of the planned and ongoing studies five have published protocols [75–79]. Overall this supports the findings in Gorst's [80] recently updated systematic review which reports the increase in COS development studies and the increasing involvement of patients and carers.

Discussion

This study has described the different data collection methods used by COS developers in order to elicit patient and carer views on their preferred treatment outcomes, and has focused specifically on the reported use of methodology and methods within associated qualitative research. To our knowledge it is the first review to focus specifically on the use and reporting of qualitative research in COS development to date.

We have used the COMET database to identify COS studies. The database is based upon a systematic review of relevant studies and is regularly updated to ensure that new studies are added as they become available [4]. However, it is possible that there may be a lag time before studies are added to the database, or that COS relevant studies are not indexed or reported in ways that would mean they are captured within the database. We did perform reference searches of papers identified and found additional studies via this method. Therefore whilst the COMET database is an appropriate source of COS studies based on systematic review methodology, there is a possibility that there may be additional relevant studies not captured here. Furthermore, the focus of this review has been on participation in COS exercises. That is, we were concerned with the participation of patients and carers as research participants contributing data to the development of COSs. Of course patients and carers can also contribute to COS development via involvement in the research process as research partners and advisors, and in doing so influence the research and outputs. Our review has not focused on this involvement, which may not always be well reported and detailed in the outputs of COS studies. Further work to examine patient and carer involvement and its contribution to COS development would be useful. Recent work focused on patient and carer involvement demonstrates that this is a key issue that should be considered by researchers in the field [81].

To date, patients have participated in exercises that both identify relevant outcome domains for consideration in a COS, such as interviews, focus groups, and surveys, and also in the prioritisation and consensus methods that finalise a COS. However, the number and types of participants taking part in these, particularly patients and carers, were sometimes difficult to discern from the papers included in this review. Where participant numbers were reported, proportionately more patients participated in methods designed to identify relevant outcome domains for consideration, whilst Health Professionals were represented more than patients in prioritisation and consensus methods.

In this sample, qualitative and survey approaches have included patients more than Health Professionals to identify outcome domains. These methods may help incorporate patient perspectives that might otherwise go unheard, via the inclusion of patient preferred outcome domains in subsequent prioritisation and consensus methods. However, in prioritisation exercises (primarily Delphi methods in COS to date) where participant perspectives are aggregated and quantified then absolute numbers of participants from different stakeholder groups will influence outputs, particularly where views differ substantially between patients and carers and other stakeholder groups. Our observation that patients appear to be in the minority in these methods should be cause for reflection, although even if the number of participants from different stakeholder groups were balanced, there is some evidence to suggest that patients and carers rate many or all outcome domains as important in such exercises [31, 37]. If this were the case then other stakeholder views may dominate as the outcome domains they do not value, on aggregate, will not be taken forward to the final COS. The inclusion of qualitative research to incorporate patient and carer perspectives as a precursor to group consensus approaches will not necessarily guarantee that patients' views are taken forward to the final COS.

In consensus meetings and conferences, one might expect Health Professionals to have more representation, as demonstrated here. The impact of patients and carers on outputs in these circumstances may well depend on the process and means by which their views are facilitated and accommodated, and on who takes part [81], as much as absolute numbers present versus other stakeholder groups.

Interestingly, one of the COS exercises we identified was expressly focused on understanding patient views and developing a patient core outcome set [30], building on the OMERACT work in rheumatoid arthritis. This approach does not rely on the integration of Health

Professional and patient and carer views in a single COS exercise. Rather, it explicitly acknowledges that patient views are likely to be different to those of other stakeholders and therefore need specific consideration.

All of the qualitative research reviewed here was utilised as a means to ensure that patient and carer perspectives on outcome domains were accommodated in COS development processes. However, a key observation from this review is that some of this research (2 out of 10 papers) appear to have been designed and conducted for other primary research aims, not associated with COS development. Exceptions to this are Sanderson [30], Allard [16] and Arnold [24]. The remaining five papers [21, 32, 34, 35, 37] discussed outcomes with patients and carers but it is unclear whether the information was collected specifically with the intention to include it in a COS exercise. The availability of related research which is ready to feed into COS development, and the desire to include patient perspectives when specific COS-focused primary qualitative work is potentially time and resource intensive, could explain this. However, it does raise questions about the precise applicability of the underpinning qualitative research.

None of the papers stated a clear overarching qualitative methodological framework. Three [19, 24, 30] mentioned Grounded Theory, but only in descriptions of analytical approach. This may well be perfectly justifiable, for example if COS related qualitative research is being undertaken from an overtly generic qualitative research standpoint [82, 83], though to date there does not appear to have been any reflection on this in the primary COS papers, or the COS methodological literature. There are longstanding debates within the qualitative methodological literature [82, 83] about the use of methodological frameworks (e.g. grounded theory, phenomenology, ethnography), the coherency of underpinning research methods, and suitability for specific research aims. These have generally been in response to generic qualitative approaches that mix and match research methods, and which are more common in health-related research.

Reflection on methodology may help to further define the purpose and role of qualitative research in COS development. For example, if the primary aim is to understand and explain patients' perspectives as a means to influence COS development then an approach such as Grounded Theory may be appropriate; if one argues that the lived experience of illness and treatment is of chief concern as it describes the essence of disease experience which we are trying to improve via trial research then a phenomenological framework may be informative; or if we are simply wanting a pragmatic precursor that lists 'patient priorities' from descriptive accounts prior to COS prioritisation exercises, then forms of generic descriptive qualitative research may suffice. Whilst to our knowledge these issues have not been considered in COS research, suitable methodological frameworks have been discussed in analogous outcome related work in the patient reported outcome development literature concerning content validity [84]. It would seem that there are very clear parallels between this work and COS qualitative research.

Thinking about data collection methods specifically, this review demonstrates the use of interviews, focus groups, and a combination of these. Whilst there has been some recent attention to this in the methodological literature [85] empirical comparisons of the outputs and relative merits of different methods is needed in this developing area. Some of this work is currently underway (S3 appendix).

The qualitative papers reviewed note limitations around recruitment and diversity of samples. The reporting of sample characteristics is also variable. This is important when considering the generalisability (transferability in qualitative terms) of findings. Implicitly, COS development for trials assumes the generalisability of the final COS to varied populations and settings [81]. Conversely, qualitative approaches may not necessarily lay claim to widespread

Table 4. Reporting recommendations for qualitative research methods in COS development.

1.	Research aims and relationship with broader COS development process
2.	Sampling approach
3.	Type of data collection methods (e.g. interviews, focus groups, combination); content and derivation / justification (e.g. topic guide)
4.	Analytical approach and justification
5.	Sample characteristics and participants numbers
6.	Findings related to outcome domains (concordant with research aims)
7.	Report approaches to ensuring rigour (e.g. multiple perspectives on the data, respondent validation) and consider reflexive content
8.	Discuss strengths and limitations of approach

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generalisability, acknowledging that patients' and carers' perspectives may vary, for example, in time, place and according to cultural factors. In addition to clear reporting of sample characteristics to aid judgements of transferability this issue needs acknowledgment. This has been addressed in some COS work, for example with work to culturally validate a patient core set amongst non-white patients in rheumatoid arthritis [86]. Outcomes and their importance in health research is often a difficult concept for patients and carers to understand [16, 85]. The data collection methods used may have a direct impact on the depth of explanation of outcomes required [81]. For example, qualitative methods allow participants to talk about their experiences of illness without the need for an in-depth understanding of outcomes [87]. There is currently no guidance on how to discuss outcomes with patients and carers in qualitative research. The sharing of best practice and the publication of topic guides will aid future COS work [81, 85].

There are some fairly simple reporting recommendations (Table 4) that we would make for future qualitative COS work which include: clear reporting of aims in relation to the COS development; sampling and sample characteristics; data collection methods and derivation; use and reporting of the topic guide; data analysis; overt description of findings in the context of the COS; and reflection on strengths and limitations of approach. Beyond this we would suggest that there is a need for more fundamental consideration of the role of qualitative methods in COS and related methodological approaches, of the relative merits of different data collection approaches in terms of knowledge produced and time and resource requirements, as well as claims to generalisability.

Supporting information

S1 Appendix. Planned and ongoing studies.
(DOCX)

S2 Appendix. Planned and ongoing studies using qualitative methods.
(DOCX)

S3 Appendix. Unpublished work.
(DOCX)

S4 Appendix. PRISMA statement.
(DOC)

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Please note:

S1 Appendix - Planned and ongoing studies, can be viewed at Appendix 1

S2 Appendix - Planned and ongoing studies using qualitative methods, can be viewed at Appendix 2

S3 Appendix – Unpublished work, can be viewed at Appendix 3 and

S4 Appendix – PRISMA statement, can be viewed at Appendix 4

2.2. Summary

This chapter addressed objective 1 of the thesis (see Chapter 1 section 1.6.2.). It has provided insight into current practice regarding the use of qualitative research methods and the participation of patients and carers in COS development.

The following chapter (Chapter 3) is a narrative review that aimed to explore and describe the differences between qualitative data collected through face-to-face focus groups and data collected through online focus groups.

CHAPTER 3: A NARRATIVE REVIEW COMPARING QUALITATIVE FACE-TO-FACE AND ONLINE FOCUS GROUP DATA COLLECTION METHODS

3.1. Introduction

Focus groups are increasingly used as a qualitative data collection method in health research in order to understand the personal perspectives and experiences of illness and healthcare provision (94, 107). The main differentiating feature of a focus group compared to an individual interview is the within-group interaction (93, 94, 108). Group interaction provides the researcher with an insight into how groups interact with each other and can highlight the differences and similarities between participant views and how they can change throughout the course of the group discussion as a consequence of interaction with the other participants (109). Well-facilitated focus groups aim to provide an environment whereby participants may feel comfortable in voicing their personal opinions and questioning those of others therefore, focus groups can be appropriate forums in which to discuss sensitive topics (93, 95, 110-112). Kitzinger suggests that the more confident participants may pave the way for quieter members of the group to contribute, and the group as a whole can provide support to each other (94). Additionally, Powell suggests that the supportive environment of focus groups can boost morale and confidence in participants (113). However, organising and conducting qualitative research, and in particular focus groups, can be time and resource intensive. Participants may be unable to travel to a focus group venue due to their geographical location, personal circumstances and/or their health, participants may not wish to discuss their views in a group, and there may not be time to discuss the topic in-depth with the participants (114-116).

Use of the internet, and in particular social networking sites, have become part of our everyday lives and in 2017 90% of households in Great Britain (GB) had internet access (117) and worldwide there were 2.46 billion social media accounts (118). Public access to computers and/or the internet is increasing all the time but it is important to remember that not everyone will have access to these facilities and therefore some potential participants may be excluded (119-122). Despite this, online focus groups may offer an alternative approach to traditional face-to face methods.

There are two different types of online focus groups, synchronous and asynchronous. Synchronous focus groups are conducted in real time and can be in one of two formats: (a) spoken data collection using audio-visual technology such as Skype or (b) text-based discussions held over email or via a chat room or forum (97, 123). Participants in synchronous audio-visual groups are able to see each other and have real-time discussions. Ingram surmised that because participants would be able to see each other the data collected by this method are likely to be similar to that collected in face-to-face groups (124). Audio-visual focus groups come with their own challenges such as participants finding the technology problematic or distracting (125, 126). Synchronous text-based groups are very similar to asynchronous groups in that they both produce textual data; however, the amount of time participants have to consider and type their comments varies greatly between the two. Comments in a synchronous text-

based group are typed spontaneously and if they are not quick enough in typing their responses participants may find that the conversation has moved on (119). Asynchronous focus groups usually take place in online forums, chatrooms or via email and can last for several days or weeks (98, 111, 120, 127, 128). The participants are able to log in and respond at a time convenient to them (96, 97). Asynchronous group participants can often post replies at any time during the day, potentially giving them longer to think about and construct their replies and comments.

To date, researchers have used different face-to-face methods in their studies (99, 114, 116, 129) or a mix of online and face-to-face methods such as; face-to-face interviews and online focus groups (130), online and face-to-face interviews (131), and face-to-face interviews and online chat forums (128).

This narrative review addresses objective 2 of the thesis (Chapter 1, section 1.6.2).

3.2. Methods

3.2.1. Search

Eligible papers were identified through Traditional Pearl Growing methodology (132). This approach was selected because it became apparent from early scoping searches that eligible literature was poorly indexed and distributed across several disciplines such as health, education, the social sciences, business, marketing and psychology (133).

3.2.2. A summary of Traditional Pearl Growing methodology

The use of Traditional Pearl Growing search techniques is recommended when seeking to inform evidence-based practice; evidence-based, clinically competent care based on the most appropriate recent knowledge (134, 135). It seeks out pre-filtered evidence (retrieves similar content regardless of the terminology used by individual authors) and can be used in conjunction with other methods (132). It differs from other search methods because it uses indexed keywords from chosen articles rather than using a formalised systematic search strategy such as a building block strategy (136). Pearl Growing can be helpful when literature is scattered across a number of different databases and disciplines, or the author has limited knowledge about the evidence in a particular subject area (132, 133). Traditional Pearl Growing involves: i) the identification of a key paper (Pearl) (137) in the area of research; ii) the identification of the keywords and terms, quality filters, limiters and thesaurus-based words the paper is indexed

under in a database; and iii) using those terms to search the database for other relevant articles then repeating these steps in other databases. This approach is undertaken until no new evidence is found (132). The process, assumes that other relevant articles are indexed in the same way as the pearl article; for this reason Pearl Growing may not be regarded as truly systematic for those researchers developing a systematic search (132, 133). If there is inconsistency in indexing, then relevant articles may be missed using this methodology. To overcome this limitation it is suggested that reference and citation searches of the included papers are undertaken (133).

The “pearl” paper (137) was identified through initial scoping searches. This paper was the only one returned from the scoping search that reported on similar aims to this review. The initial scoping search used a combination of the keywords assigned to the pearl paper: qualitative methods, online, focus groups. During March and April 2016 searches of the following electronic databases were undertaken: Pubmed, the Social Sciences Citation Index (SSCI), Scopus, Web of Science, Proquest and the University of Birmingham library database. Proquest is a collection of 38 databases covering many different disciplines such as Education, the social sciences, business, marketing and psychology. Similarly, the University of Birmingham library provides access to databases covering these disciplines. The references and citations of eligible papers were also searched to ensure no papers were missed due to differences in indexing and keywords (133). An example search strategy is in Appendix 5.

3.2.3. Eligibility criteria

3.2.3.1. Inclusion criteria

Papers were included if they specifically reported on comparisons between face-to-face focus groups and online synchronous and/or asynchronous focus groups.

Papers were also included if they reported on some comparisons between face-to-face focus groups and online synchronous and/or asynchronous focus groups although this was not a specific aim of their research.

3.2.3.2. Exclusion criteria

Narrative or systematic reviews comparing the similarities and differences between face-to-face focus groups and online synchronous and/or asynchronous focus groups were excluded.

Searches were limited to papers published from 2000 to-date. The rationale was based on the assumption that any research on the subject prior to this date was likely to be outdated in today's online environment due to the rapid advances in technology since the start of the millennium (123).

3.2.4. Data extraction and reporting

A data extraction proforma (Appendix 6) was developed and data were extracted from the included papers against the criteria listed below:

i) The differences and similarities in the recruitment and sampling strategy for online and face-to-face focus groups;

ii) The participant characteristics;

iii) The similarities and differences in the analytical approach to the data collected by online and face-to-face groups;

iv) The analytical approaches to comparing data sets;

v) The reported differences in the findings and the depth of data produced by both methods;

vi) The reported participant interactions in online groups and face-to-face groups;

vii) Any reported information on the resources required to carry out the research.

Data were summarised descriptively and a summary of the advantages and disadvantages of collecting qualitative data by face-to-face focus groups and online focus groups presented.

3.3. Results

The searches returned 2464 papers, 11 of which were duplicates. After the screening of titles and abstracts, 16 papers appeared to be potentially eligible. After reading the full papers three more papers were excluded. This resulted in 13 eligible papers plus the initial “pearl” paper (137). Therefore, this strategy identified 14 eligible papers. Reference and citation searching found an additional 14 papers of which six were excluded, leaving eight eligible papers. In total, 22 eligible papers were included. See Figure 3.1 Paper selection process and Table 3.1 Summary of included papers.

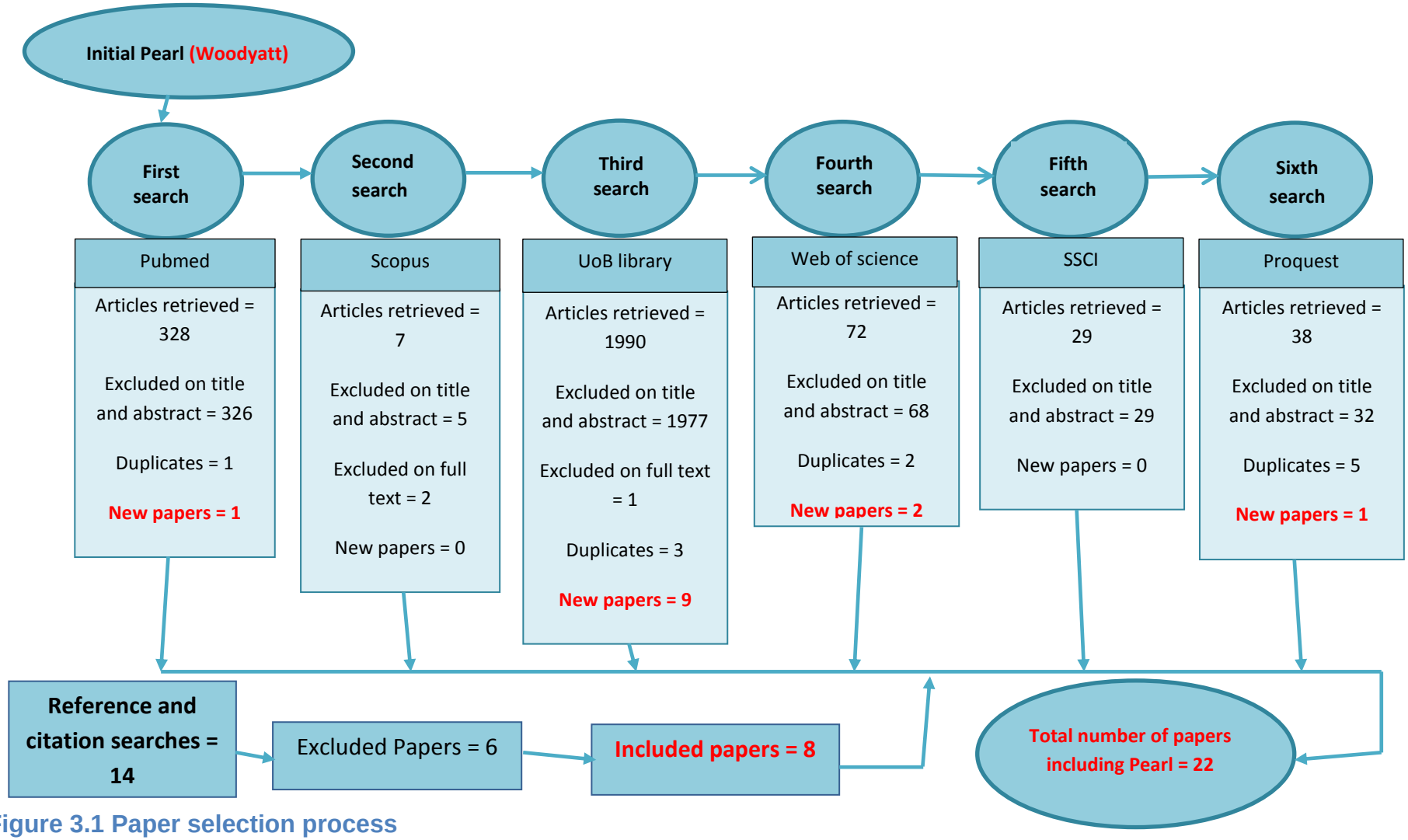


Figure 3.1 Paper selection process

Table 3.1 Summary of included papers

Author	Year	Discipline	Face-to-face (synchronous)	Online text (synchronous)	Online text (asynchronous)	Combined forum and chat~(both)	Audio-visual (synchronous)	Audio only (synchronous)	Simulated* (synchronous)	Avatar^ (synchronous)
Papers that set out to compare the use and utility of face-to-face and online focus groups										
Abrams et al (138)	2015	E	Y	Y			Y			
Bruggen et al (139)	2009	MR	Y	Y						
Campbell et al (140)	2001	H	Y	Y						
Cheng et al (141)	2009	MR	Y	Y				Y		
Dewitte et al (142)	2002	MR	Y	Y						
Gadalla et al (143)	2016	MR	Y							Y
Graffigna et al (144)	2006	SS	Y	Y	Y	Y				
Guise et al (145)	2007	H	Y		Y					
Ingram et al (124)	2015	H	Y		Y		Y			
Krol et al (146)	2014	H	Y		Y					
Nicholas et al (127)	2010	H	Y		Y					

Author	Year	Discipline	Face-to-face (synchronous)	Online text (synchronous)	Online text (asynchronous)	Combined forum and chat~(both)	Audio-visual (synchronous)	Audio only (synchronous)	Simulated* (synchronous)	Avatar^ (synchronous)
O'Neal (147)	2009	E	Y		Y					
Reid et al (148)	2005	MR	Y	Y						
Schneider et al (149)	2002	H	Y	Y						
Synnot et al (98)	2014	H	Y		Y					
Underhill et al (150)*	2003	SS	Y	Y					Y	
van Eeden-Moorefield et al (151)	2008	SS	Y	Y						
Woodyatt et al (137)	2016	H	Y	Y						
Papers reporting comparisons between face-to-face and online focus groups, although not a specific aim of the study										
Banfield et al (152)	2014	H	Y		Y					
Brubaker et al (153)	2013	H	Y	Y						
Perdok et al (154)	2016	H	Y		Y					
Walsh et al (155)	2009	H	Y	Y						

H= Health, SS = Social Sciences, MR = Market Research, E = Education.

~Combines asynchronous forum and synchronous chat. Participants take part in a forum for 2 days, a chat on the evening of the second day and then a final day on the forum.

*The internet-simulated groups were designed to replicate online groups where participants are geographically dispersed, with no access to verbal and non-verbal cues.

^In avatar groups, the participants enter an online world taking on the persona of an avatar, which can then interact with other avatars in the same environment.

3.3.1. Summary of the data collection methods reported by the included papers

All of the papers conducted face-to-face focus groups. Thirteen (59%) also conducted synchronous online focus groups (137-143, 148-151, 153, 155), seven (32%) asynchronous online focus groups (98, 127, 145-147, 152, 154) and two (9%) used both synchronous and asynchronous online methods (124, 144). Three (14%) of the papers (151, 152, 154) reported that they chose to use online methods as a way of triangulating the data collected with those collected from the face-to-face groups. The remainder of the papers reporting using face-to-face and online focus groups to compare the outputs from both methods and/or to assess the feasibility of using online focus groups.

3.3.2. Recruitment and sampling strategy

Nineteen papers (86%) chose to use the same approach to recruitment for both the online and face-to-face groups (98, 124, 127, 137-139, 141-144, 146-151, 153-155). Three (14%) of these papers reported using a third party, such as a professional qualitative research company, to recruit participants on their behalf (124, 143, 149). For the other papers, members of the research team undertook recruitment. Three (14%) papers chose to approach recruitment to the face-to-face groups differently to how they recruited to the online focus groups (140, 145, 152). For example, in Guise's study, face-to-face participants were recruited via letters sent through support group committees and online participants were recruited via messages posted on a web-based support group (145).

The majority of papers (n=13 59%) reported using a purposive approach to sampling (98, 124, 127, 137, 140-142, 144, 146, 148, 149, 153, 154), and two (9%) reported using a convenience sampling approach (150, 155). Ten papers (45%) reflected on the value and effectiveness of the chosen recruitment and sampling strategy (127, 137, 140, 141, 146, 151-155). For example, Nicholas and Woodyatt reflected on the bias which they may have introduced by allowing participants to select which focus group format they took part in or to allocate participants to either a face-to-face focus group or an online focus group based on availability and location (127, 137). Krol considered the difficulties they faced in recruiting young children and adolescents to both the face-to-face and online asynchronous text-based focus groups (146). They surmised that adolescents, in

particular, would be interested in the online asynchronous focus groups based on the success of paediatric patients taking part in online asynchronous groups reported by Tates (111). However, the response rate for these groups in Krol's study was just 2%. van Eeden-Moorfield reported on the success of recruitment to their face-to-face and synchronous online text-based focus groups (151). They put their success down to using gatekeepers to access the relevant population and of being able to adapt their recruitment approach when difficulties became apparent. Regarding the asynchronous groups, Perdok suggested that busy professionals appreciated the option to take part in an online discussion as this took away the time-consuming necessity to travel to a particular venue (154).

Of the papers that used the same recruitment strategy for each data collection method, five papers (23%) did not state, or it was difficult to discern, how they allocated participants to either online or face-to-face groups (124, 139, 141, 143, 154). Four papers (18%) reported that the participants were allowed to self-select which group they participated in (137, 146, 147, 151), and six (27%) reported that participants were randomly allocated to groups (138, 142, 144, 150, 153, 155). Three papers (13%) used a variety of methods such as inviting those who were unable to take part in a face-to-face focus group to take part in an online focus group (98, 127, 149). In one study, the same participants took part in both a face-to-face and an online focus group (148).

3.3.3. Reported sample characteristics

The number and type of sample characteristics reported in the included papers varied. Five papers (28%) reported a list of characteristics including age, gender, ethnicity, socio-economic information, disease duration and profession for both face-to-face and online focus groups (98, 137, 140, 153, 155) (one of which used asynchronous online groups (98) and the other four synchronous online groups). The remainder of the papers described three or fewer criteria such as age, gender, and profession. Of these, nine conducted synchronous online focus groups (138, 139, 141-143, 148-151), six asynchronous online focus groups (127, 145-147, 152, 154) and two both synchronous and asynchronous (124, 144). Five papers reported having geographically dispersed online participants across the nation in which the research was undertaken: Australia, Netherlands, USA, USA, and the Netherlands respectively, but the face-to-face focus groups did not include geographically dispersed participants (98, 146, 149, 151, 154). Participants in both the online and the face-to-face groups were dispersed (USA, Taiwan, and Australia respectively) in three of the papers (141, 152, 153) but Nicholas was the only paper to include international participants, from Canada and England, in their asynchronous online groups (127).

3.3.4. Analytical approaches used to compare data between different data collection methods

The papers used a range of approaches to make comparisons between the different types of data collected. Three papers chose to compare data using qualitative methods alone (98, 144, 147), eleven (50%) used only statistical methods, such as counting and scoring systems, or they used statistical methods in combination with qualitative methods (124, 127, 137-139, 141, 142, 148-151). These included comparisons on the length of discussions (124, 137, 151), the proportion of words used by the moderator compared to the participants (137, 148), and the number of relevant and irrelevant comments (150). Gadalla surveyed participants for their views on the effectiveness of the groups (143). Krol did not state how comparisons were carried out (146). For a summary of the methods used to compare the datasets see Table 3.2.

Table 3.2 Analytical approaches to comparing datasets

Paper	Reported methods of analysis	Purpose of analysis
Abrams (138)	Content analysis. Software-based automated linguistic analysis.	To compare data richness across mediums, the frequency of related and unrelated data, word counts.
Banfield (152)*	Thematic analysis using *a priori* and *in vivo* codes.	To identify priorities for further research.
Brubaker (153)*	Detailed evaluation and review of transcripts plus field notes. No further explanation provided by authors.	To gather women's knowledge and attitudes about research participation.
Bruggen (139)	Subjective analysis carried out by four experts in qualitative analysis. Objective evaluation relied on unbiased counts carried out by two judges	To compare the depth of data, the breadth of data, group dynamics, and non-verbal communication.

Paper	Reported methods of analysis	Purpose of analysis
Campbell (140)	Grounded theory-based approach (inductive). Kappa coefficients used to determine the level of observed-to-expected agreement.	To compare data across datasets on participants perceptions of screening, diet and physical activity. To determine the level of observed-to-expected agreement.
Cheng (141)	Statistical analysis of data.	To evaluate equality of participation, group interaction, self-disclosure, quantity and quality of information.
Dewitte (142)	Three different coders read each manuscript and scored the responses to individual answers person by person.	To compare the breadth and depth of the data. Papers were scored on a five-point scale (high numbers = higher disclosure).
Gadalla (143)	A reflective approach to analysis. Semi-structured survey	To compare data quality, the conduct of the avatar based focus groups (AFGs), and the moderator's reflections. Semi-structured survey "offered descriptive

Paper	Reported methods of analysis	Purpose of analysis
		reflective discussion on participants' experience and their differing viewpoints of the effectiveness of AFGs".
Guise (145)	Discourse analysis in the context of discursive psychology, which draws insights from conversation analysis.	To analyse conversations and interactions between participants in each dataset.
Ingram (124)	Use of a computer program. Two Judges/three market researchers to compare qualitative findings	To compare the number of words and answers generated, the average number of words, the amount of interaction, relevance of answers, the depth and the breadth of answers given.
Nicholas (127)	Content analysis.	To compare similarities and differences in the data between data collection methods. Such as word counts, group dynamics, outcomes, and contextual issues.

Paper	Reported methods of analysis	Purpose of analysis
O'Neal (147)	A coding system to develop themes and to capture the essence of their meaning.	To identify common themes between datasets and the interaction between participants.
Perdok (154)*	Thematic analysis, frequency analysis of codes.	To identify the opinions of midwives. To assess the frequency of codes.
Reid (148)	Statistical analysis of data.	To compare equality of participation, interaction, self-disclosure, productivity, number of questions asked by the facilitator.
Schneider (149)	Analyses of variance.	To identify the number and length of comments, the proportion of off topic discussions and the number of statements of agreement with prior statements made by other participants.

Paper	Reported methods of analysis	Purpose of analysis
Synnot (98)	Thematic analysis underpinned by an interpretivist framework.	To compare themes generated by both methods, off-topic discussions, depth of data, and participant interaction,
Underhill (150)	Transcripts independently coded by four raters. Interrater reliability analysis.	To compare the number of participation attempts, the number of relevant comments, the number of irrelevant comments, the number of disagreements, and the total number of comments for each participant.
Van Eeden Moorfield (151)	Constant comparative method of analysis. Content analysis of transcripts.	To carry out a simple word count, to measure the breadth of the collected data. Depth was coded on a scale of 1-10 (1= simple answers).
Walsh (155)*	Quantitative analysis. Qualitative analysis - Grounded theory approach.	To identify descriptive code words. To count the number of items related to the study (dietary habits). No further details provided.

Paper	Reported methods of analysis	Purpose of analysis
Woodyatt (137)	Quantitative analysis and qualitative analysis (thematic analysis using inductive and deductive coding).	To compare word count, length of discussion, the proportion of words used by a moderator, intragroup conflict.

*Comparison between data collection methods was not the aims of these papers and therefore do not contain details on how the datasets were compared.

3.3.5. The depth of data produced

Depth of data describes the characteristics and qualities of qualitative data that make it sufficient to facilitate an understanding of how research participants make sense of their experiences and the meanings they place on those experiences (88, 89, 156). Seventeen (77%) of the papers reported which of their chosen data collection methods they perceived as generating greater context and data richness around the identified themes and ideas. Nine (41%) of the papers (98, 127, 138, 139, 142, 146, 149, 153, 155) reported that face-to-face focus groups produced the greatest depth of data, and that richer, more useful data, were elicited (127, 142, 146) even though some of those data were perceived as “off-topic” (98). Nevertheless, the authors concluded that face-to-face groups provided an extensive exploration of the topic under discussion. When comparing the data produced in face-to-face focus groups to those produced in online focus groups, they made the following observations: synchronous online groups tended to elicit short, superficial answers lacking contextual detail and sometimes became more like a question and answer session (138, 139, 149). Abrams was concerned that the ability of participants to see themselves on the screen in audio-visual groups hindered self-disclosure and non-verbal expressions (138). Dewitte reported a serious problem with their synchronous online groups suggesting that they failed to generate in-depth data from the participants. The input of participants in the online groups remained at the same level throughout whereas in the face-to-face groups participants

became more involved as the discussion progressed (142) and Nicholas also found that their asynchronous group lacked contextual detail (127).

Contrary to the above, three papers (14%) reported that synchronous online groups produced more in-depth data compared to face-to-face groups (137, 141, 151). Cheng reported that compared to the face-to-face groups the synchronous online audio groups produced superior results (141) in that the replies were of a higher quality, produced more information, and participants acted with greater openness (141). Both van Eeden Moorefield and Woodyatt suggested that the in-depth answers elicited online might be due to the perceived anonymity of the environment, which in turn can give participants the confidence to talk about the issues more openly (137, 151). Similarly, Ingram found that the online asynchronous text group provided slightly more substantial answers (e.g. more distinctive, relevant to the research aims, and participants provided the attitude and reasoning behind their answers) when compared to the face-to-face groups (124). The remaining four papers (18%) all rated online focus groups and face-to-face focus groups as equal in the information and the depth of data they produced (143-145, 150). Five papers (23%) did not report on the depth of the data produced by each method but they did report that all the methods used generated similar topics and information (139, 147, 148, 152, 153). Figure 3.2 provides a visual summary of the authors' perceptions of which data collection method produced the greatest in-depth data.

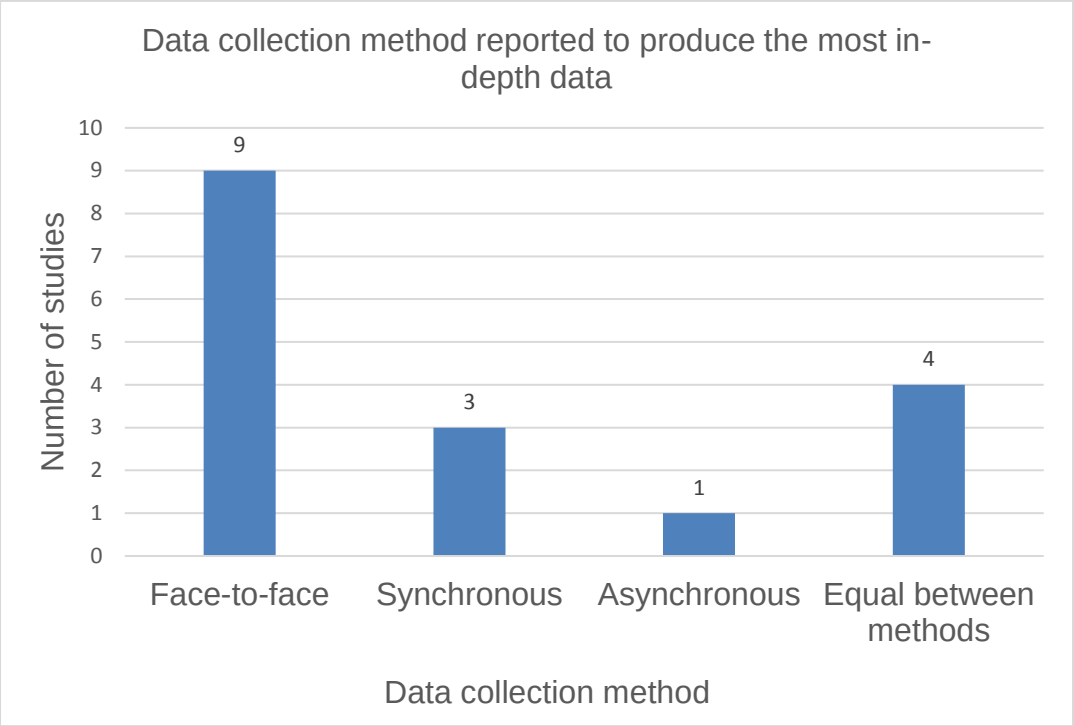


Figure 3.2 Data collection method reported to produce the most in-depth data

3.3.6. Participant interaction

Four papers, two (9%) using online synchronous methods (140, 151) and two (9%) using online asynchronous methods (145, 152) did not report on the level of participant interaction. Five papers (23%) using online synchronous methods (138, 142, 148, 149, 153), four (18%) using asynchronous methods (98, 127, 146, 154) and one (4%) using both synchronous and asynchronous (124) reported that face-to-face groups had the most interaction between the participants. Reid, who compared face-to-face focus groups with online asynchronous groups, found that face-to-face participants showed more empathy, agreement, and solidarity compared to the online focus groups (148).

In contrast, three papers (13%) all using synchronous online methods, found that the online groups produced more interaction (137, 141, 155). Walsh suggested that interaction between participants in their online focus groups was facilitated by the use of emoticons, capitalising of text for emphasis and using an asterisk when making corrections (155). However, a point to note is that participants in this study were young college men familiar with communicating online. Cheng concluded that synchronous online focus groups provided more interaction and believed that this was due to the perceived anonymity and distance between participants providing the freedom to express opinions (141). Similarly, Woodyatt believed that participants felt confident to discuss their personal experiences on a sensitive subject because of the perceived confidential and anonymous online environment (137). The remaining papers, three using online synchronous methods (139, 143, 150), one using online asynchronous (147) and one using both synchronous and asynchronous (144) reported that interaction was equal between the groups. For instance, Gadalla who used an online synchronous group found that participants in both the face-to-face focus groups and the online focus group interacted and shared their opinions equally (143). Of the two online synchronous methods (text and audio-visual) used, Abrams, reported that only the audio-visual method had participant interaction which was comparable to the face-to-face groups (138). See Figure 3.3 for a visual summary of the authors' views on which data collection method produced the greatest participant interaction.

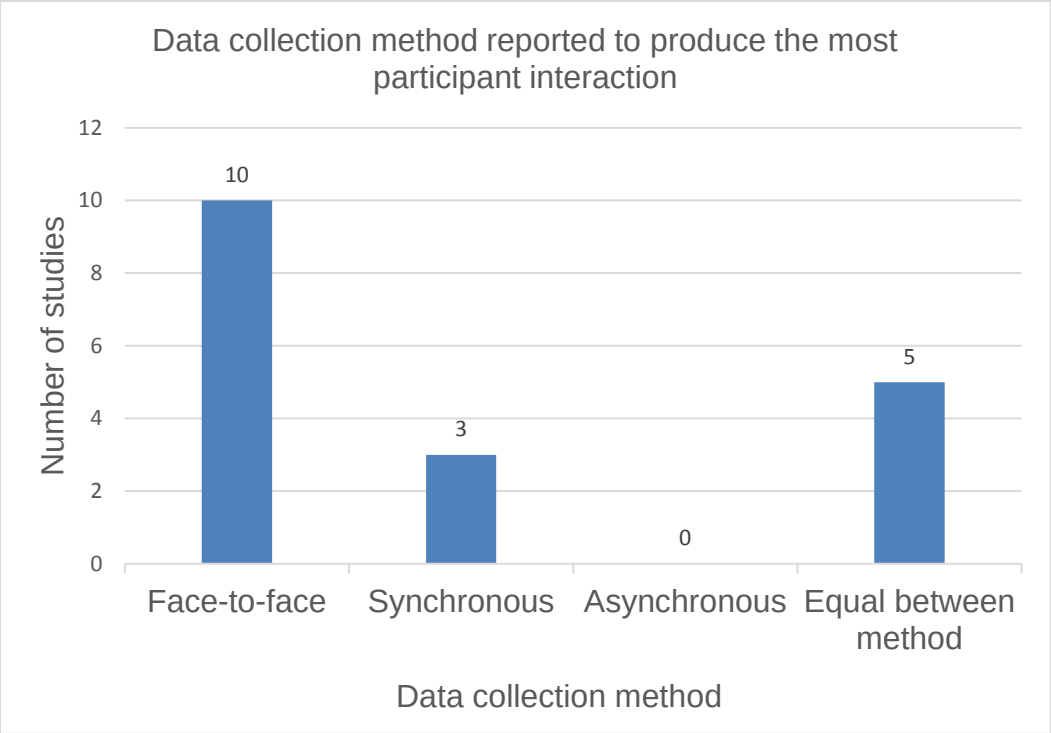


Figure 3.3 Data collection method reported to produce the most participant interaction

3.3.7. Resources

Nine papers (41%) reported on the length of time to run the focus groups (98, 137, 141, 143, 146, 148, 151, 152, 155). For example, Reid commented that the synchronous online focus groups lasted twice as long as the face-to-face groups but found that the online groups generated less communication (148). Woodyatt suggested that the reason why the online synchronous groups took longer was due to “non-data elements” such as off-topic discussions, intragroup conflict, and the number of words used by the moderator (137). Asynchronous focus groups collect data in a different way to data collected by face-to-face and synchronous focus groups and they were reportedly conducted over a period of one month

(98, 152) or one week (127, 146, 154). Four papers using online synchronous (140, 142, 149, 155) and one (146) study using online asynchronous methods reported compensating participants for their time. One (146) gave out gift certificates, three (140, 142, 155) provided monetary remuneration of €10, $25 and $20 per participant respectively and one (149) reported that participants received compensation for their time but no further details were provided. Interestingly, Campbell (140) only provided compensation to the face-to-face participants, whereas the others (142, 146, 149, 155) compensated all participants regardless of data collection method. None of the included papers provided any detailed information about the resources required to conduct face-to-face focus groups and online synchronous or online asynchronous focus groups. The papers did not report information about the costs or time associated with items such as room hire, web set up, transcription, refreshments, and travel expenses.

3.4. Discussion

This review compared the nature of qualitative data generated by face-to-face and online focus groups. The majority of the included papers reported recruiting participants to the different data collection methods, in the same way, using a purposive approach (98, 124, 127, 137, 140-142, 144, 146, 148, 149, 153, 154). The reporting of the sample characteristics was variable between the papers as were the methods used to analyse and compare the data. Nine (41%) of the authors reported that the face-to-face groups produced the richest data (98, 127,

138, 139, 142, 146, 149, 153, 155) and ten (45%) that the face-to-face groups had the most participant interaction (98, 124, 127, 138, 142, 146, 148, 149, 153, 154). However, this finding is not definitive as other papers found that online methods produced a better depth of data and better participant interaction (137, 140, 141, 151, 155). Four papers reported that face-to-face and online methods produced equally rich data (143-145, 150) and five reported equal participant interaction (139, 143, 144, 147, 150). Overall, based on the findings of this review, face-to-face focus group data collection methods appeared to produce a greater depth of data and greater participant interaction.

In line with qualitative research in general, over half of the papers (n=13 59%) reported purposively sampling for participants that could help to answer their research questions (98, 124, 127, 137, 140-142, 144, 146, 148, 149, 153, 154). Often location and/or experience with technology determined the allocation of participants to either a face-to-face focus group or an online focus group. This approach, however, may lead to a difference in characteristics between the online and face-to-face focus group participants which will need to be taken into account when reporting research results (111). There is a view that those taking part in online research may be younger and more educated (157) and Fox suggested that online research can be dependent on participants' socio-economic status (119). Three of the included papers agreed with this (98, 140, 153), although Banfield found that online participants were middle-aged and well educated rather than younger and well educated (152). Access to the internet is increasing all the time and so in the future, this general assertion may no longer

hold true (117). However, it is important to note that having access to the internet and to social media platforms does not automatically mean that everyone will have the required skills and ability or the desire to take part in this type of group.

The included papers reported using a variety of analysis methods. However, for the purposes of comparison, all the datasets (face-to-face and online) within each study were analysed using the chosen data analysis method. This is good practice ensuring that data from both data sets are extracted against the same criteria, limiting the risk of missing relevant data, which may occur if different methods are employed (158).

Qualitative research aims to collect data rich in meaning and understanding in order to answer a specific research question. Interviews are designed to generate rich detail on individual experiences. Focus groups facilitate group interaction and the generation of group experiences and opinions. Many other aspects of a research study will have an influence on the depth of data generated, for example, the types of questions asked, direct, indirect or experiential, will influence the type of data generated. The experience and skill of the interviewer or facilitator, the training they have received, their ability to develop a rapport with the participant(s) and how they respond to verbal and visual cues can be associated with the depth of data elicited. When planning data collection it is important to consider who the facilitator will be. Should they have knowledge of the subject or not? There are advantages and disadvantages

to both of these scenarios. With knowledge of the subject, the facilitator will understand the treatments and processes the participants talk about and will know when to probe for further information. A disadvantage is a facilitator may assume they know what the participants are discussing and not probe for clarification. If that assumption is incorrect then the resulting data and interpretations will not accurately reflect the opinions of the participants. This works both ways, if a facilitator has little knowledge of the subject they may not recognise relevant information and fail to probe for clarification. An advantage of a facilitator not having knowledge of the subject is that participants may view them as impartial and feel more comfortable in expressing their personal views. It is also important to consider the relationship of the researcher to the participants, for example if they are known to each other clinically or via other means as this may also have an influence on the data generated. Similar to the characteristics of the interviewer or facilitator the characteristics of the researchers analysing the data can also influence the output. If collecting and analysing data iteratively there is the potential for this to influence the data produced and the interpretation of the data. The participants themselves also have an influence on data generation, for example, the social demographics of the participants in a focus group can influence how open the discussion is. In general, people are more comfortable if they feel they have something in common with other participants. Finally it is important to remember that not all potential participants approached about the research will agree to take part and this may result in the underrepresentation of certain sections of society.

Most of the included papers discussed the richness of data generated by each of their data collection methods. The majority (n=9 41%) of papers reporting on this found that face-to-face interactions produced the most detailed and rich data. In contrast, five papers (23%) found that online discussions provided richer data than the face-to-face groups. This finding is supported by Seale (121) who suggests that participants reveal more intimate details in a supposed anonymous environment. Consequently, the level of detail elicited from participants may be dependent on the subject matter and the data collection method used. A further explanation for the differences in data richness between methods may be the role of the facilitator. Murgado-Armenteros and Zwaanswijk suggest that a more structured intervention by the moderator is required for online groups compared to face-to-face and that they may need to take more of a leadership approach than they would in face-to-face groups (159, 160). This scenario can, however, result in the facilitator unwittingly prompting and influencing replies (159). It may also result in a question and answer session rather than a discussion (148). Conversely, Curasi (131) found that when online participants were probed for more information they provided answers as detailed as those given in the face-to-face groups. However, there is also no clear distinction in data richness between the different disciplines or indeed between synchronous and asynchronous online focus group methods in the included papers.

Ten papers found that interaction between participants in the online groups was less than that in the face-to-face groups (98, 124, 127, 138, 142, 146, 148, 149, 153, 154). This reflects the findings of Murgado-Armenteros who reports that

there can be difficulties in achieving interaction between participants in an online focus group (159), and Greenbaum who argues that the lack of non-verbal cues and difficulties establishing a presence behind the computer screen can compound the problem (161). In contrast, three papers all using text-based synchronous methods found that interaction between participants was greater (137, 141, 155). They did not find that discussions were hindered by the absence of non-verbal cues; instead, they report that online participants tend to give feedback to each other using computer speak and emojis, etc. and tend to facilitate interaction between themselves without the need of the facilitators (137, 141, 155). Abrams in their synchronous online group observed participants creating their own sense of community and belonging (138). They suggest that the desire to establish an individual presence and personality may explain the need to develop a community type atmosphere (138), although this view is in contrast to that of Murgado-Armenteros (159) who reports that cohesion is difficult to achieve in synchronous online groups.

Contrary to the findings reported by Nyguyen that there is currently a lack of evidence to support one data collection method over the others (162), this review has found that face-to-face focus groups generate more participant interaction and produce a greater depth of data compared to online groups.

There is very little in the included papers about the resources required to conduct face-to-face and online focus groups. A recently published paper by

Rupert (115) reports the findings from a study designed to specifically compare costs, recruitment, and logistics between online and face-to-face focus groups. The findings suggest that there is little difference in costs between the methods. Recruitment to face-to-face focus groups was higher and participants less geographically dispersed compared to participants in the online groups. Interestingly, Rupert reports that compared to the face-to-face focus groups the online participants were more racially diverse with a larger percentage having less than a high school education. However, others (119, 157) including four of the included papers (98, 140, 152, 153) have found that participants in online focus groups tend to be white, younger and more educated. When thinking about time it is important to note that the length of time to conduct a focus group is not necessarily a good indicator of quality. For example, a very rich short focus group may provide better quality data than a long thin group or vice versa. The review has highlighted several potential advantages and disadvantages of face-to-face and online focus groups. Table 3.3 provides a summary of these.

This review provides the first comprehensive review of face-to-face and online focus groups. However, some relevant papers may have be omitted due to using the Traditional Pearl Growing methodology to identify papers. The data presented in this review is reliant on the authors' interpretations of their data and their conclusions.

Table 3.3 The advantages and disadvantages of face-to-face and online focus groups

Face-to-face focus groups
Advantages
Can facilitate interaction between participants (88, 108, 163)
Can empower the participants (88, 93, 95, 163)
Can facilitate disclosure (even with sensitive subjects) (88, 94)
Provides the opportunity to explore unexpected topics as they arise (88)
The power of the facilitator is reduced (88)
Non-verbal cues can be observed (88, 89, 95)
Disadvantages
Can be difficult to facilitate (88)
Participants can easily go off topic (88)
One or two participants can dominate the discussion (88, 149)
Quieter members of the group may feel intimidated and therefore not contribute to the discussion (88, 89)
Geographically dispersed participants may not be able to participate (88, 149)
Some participants may feel uncomfortable talking about sensitive subjects with others (88, 94)
Transcription can be time-consuming (88)
Can be resource intensive (88)
Recruitment and organisation can be difficult (88)
Online focus groups
Advantages

Participants may feel comfortable communicating in this environment (111, 137)
A threaded discussion can easily be followed (111, 128, 157)
Text-based discussions can easily be transferred to a working document (98, 111, 128)
Use of emojis can replace non-verbal cues (127, 143)
Cost-effective – no transcription costs (155)
Geographically dispersed participants can be included (98, 120, 128)
Disadvantages
Not everyone may have access to the internet (119-122)
There may be security concerns especially if participants are using their own names/email addresses (111, 128, 157)
It can be difficult to develop a rapport with other participants (111, 128, 157)
Lack of non-verbal cues (111, 149, 157)
Logging-on difficulties/forgetting passwords (111, 128, 157)
Ensuring participants understand how to use the technology can be time-consuming (111, 128, 157)
Need to set up a platform to host the discussions (123)
Facilitators may need to prompt more to get in-depth answers (149)

3.5. Conclusions

The aim of this chapter was to review the strengths and limitations between face-to-face and online focus groups. Based on the available evidence, this review has concluded that face-to face focus groups appear to produce the most in-depth data and participant interaction; however, some papers found the opposite, particularly around online methods. It is recommended that face-to-face focus groups are used to optimise the elicitation of in-depth data through good participant interaction but researchers are free to make their own decisions about which methods to use based on the aims of their research and the available resources. Further research is required to evaluate online focus groups and their place and appropriateness in qualitative research (137). Increasingly peoples' lives are moving online, it is therefore important and timely that a good methodology for online research be established although the research community should be mindful that not everyone will want to take part in online research methods (128). To help future researchers decide if qualitative online research alone, or in combination with face-to-face methods, are suitable for their research project it is recommend that details of sampling, analysis, resource use, the differences between participant interactions and depth of data generated are reported.

3.6. Summary

This narrative review has compared face-to-face and online focus groups to address objective 2 of the thesis (Chapter 1 section 1.6.2). Together with the

findings from the review of patient and carer participation and the use of qualitative methods in COS development (Chapter 2) it has helped to inform the design of the primary research. Chapter 4 describes the methodology and methods used for the primary research using face-to-face and online focus groups and the re-analysis of interviews with adult burn patients. Chapter 5 reports the findings of this work.

CHAPTER 4: METHODOLOGY AND METHODS

4.1. Introduction

This chapter provides an overview of my research “what outcomes are important to adult burns patients that have experienced scar management therapy (The OSCAR study)”. This includes my chosen methodology, sampling, data collection, and data analysis methods. The chapter concludes with a discussion on reflexivity.

4.2. Qualitative research

Qualitative research is about understanding how participants view their social or psychological world, it tries to capture the meaning and messiness of real life by creating a framework within which to interpret it (88). It can provide rich and deep understandings of real lived experiences and can highlight differences within accounts and across accounts. Qualitative research uses diverse mediums such as text, observations, audio recordings and images as its source data rather than numbers (88, 89, 164). Qualitative research methods in health research can answer questions about what is it like to live with a certain condition. It can help researchers to understand the terms and the words patients use to describe their condition, its symptoms and treatments, and to understand what treatment outcomes are important to patients and why they are important (53, 107, 165). It explores patients’ subjective views in a natural setting rather than in an experimental setting (166).

4.3. Methodologies

Methodology explains how knowledge is gained, it provides principles to guide the research and provides a description, explanation, and justification for the methods used (88, 89, 167). Table 4.1 gives brief details of some of the most commonly used qualitative methodologies (168). I then provide detailed information on my chosen methodology of interpretive description (169, 170), which falls under the umbrella of generic qualitative research (171-173). See section 4.3.1 for a detailed account of interpretive description.

Table 4.1 Overview of some of the most commonly used qualitative approaches (88, 89, 174-178)

Methodology	Description	Relevance to my research
Ethnography	The focus is on investigating the beliefs, behaviours, and customs of groups, which define the culture of that group. It produces a detailed description and interpretation of a culture. Ethnography does not necessarily adhere to a formal theory, although this depends on the type of ethnographic study.	Ethnography originated from anthropology and its focus is on cultural practices. It was therefore not relevant to this research.
Phenomenology	Investigates the lived experience of a phenomenon concentrating on the process of experiencing.	Phenomenology originated from philosophy with the aim of understanding the nature of being and existence. This research asked participants about their experiences of burns and scarring from which patient outcome priorities were inferred, and the data generated by different

Methodology	Description	Relevance to my research
		qualitative methods were compared. Because of the pragmatic element of this research, this approach was inappropriate. If a more in-depth understanding of the experiences of burn injury were an aim of the research then phenomenology would be a suitable approach.
Grounded theory	Aims to develop a new substantive theory about a phenomenon.	Grounded theory is rooted in sociology and developed as a way to observe the influence of social interactions on human behaviour. This research aimed to understand outcomes that matter to patients through the comparison of data collected through different qualitative data collection methods. Generating a theory about outcomes was not an aim of this research

Methodology	Description	Relevance to my research
Case study	In-depth investigation of a single case or a few cases often using multiple methods and different types of data (documents, observations, interviews or focus groups).	Case studies are used when seeking an organisational, service or geographical perspective. Whereas, this study aimed to compare individual interviews with the views from focus group participants.
Narrative, life histories	Study of a certain phenomenon in peoples' lives. Produces detailed descriptions of life-stories.	Gaining in popularity in the 21st-Century narrative and life histories are used to understand phenomena in the context of participants' own development and histories. This method is certainly appropriate. However, this approach particularly lends itself to in-depth interviews only whereas the aim of this research was to compare different qualitative research methods.

4.3.1. Generic qualitative research

Generic qualitative studies aim to understand an experience or an event (171). There are two types of generic qualitative studies: those borrowing and/or combining methods from different methodologies (for example, a study may adopt the constant comparison analysis technique from grounded theory but may not use other aspects of grounded theory such as theoretical sampling) (179), and those that report no specific methodological stance (171, 172). However, this does not imply that there is no need for rigor, justification of chosen methods nor a statement on the researcher's analytical lens in the research design (171, 172, 180). Merriam states that generic studies focus on: 1) the interpretation of experiences by participants, 2) how participants construct their worlds, and 3) the meanings they place on their experiences (181).

An example of an established generic qualitative approach is interpretive description (170). This approach was first developed in the nursing field to help deliver research relevant to nursing practice (170). Findings from an interpretive description study should highlight the benefits of the research to everyday practice (169, 174, 182). Interpretive description takes the constructivist approach to research believing that realities are socially and experientially constructed and rejects the stance that objective knowledge can be obtained (170). The influence, experience, and knowledge a researcher brings to the research process should be acknowledged (169, 172). Interpretive description advocates the use of multiple methods to provide triangulation of data and the

inductive constant comparative method of data analysis is encouraged in order to place the research findings within the current knowledge base (169, 170, 172).

I feel that a generic interpretive descriptive approach fits well with the pragmatic aims of my research to inform practice through trial research. To elicit the outcomes that are important to burns patients following scar management treatment, to understand why those outcomes are important and to evaluate the feasibility of using qualitative methodology and methods to draw out this information. Additionally, as advocated by interpretive description I will be collecting and analysing data from different qualitative data collection methods (170). Interpretive description allows for the study design to fit the needs of the research and can provide an understanding of how people experience their health and disease and is appropriate in the context of understanding which outcomes are important to burns patients (174).

4.4. What outcomes matter to adult burns patients that have experienced scar management therapy? (The OSCAR study)

4.4.1. Aims and objectives of the OSCAR study

This phase of the research aimed to compare the results of the re-analysis of the semi-structured interviews conducted as part of the PEGASUS feasibility study with primary data collected via face-to-face and asynchronous online focus groups with adult burns patients, to specifically:

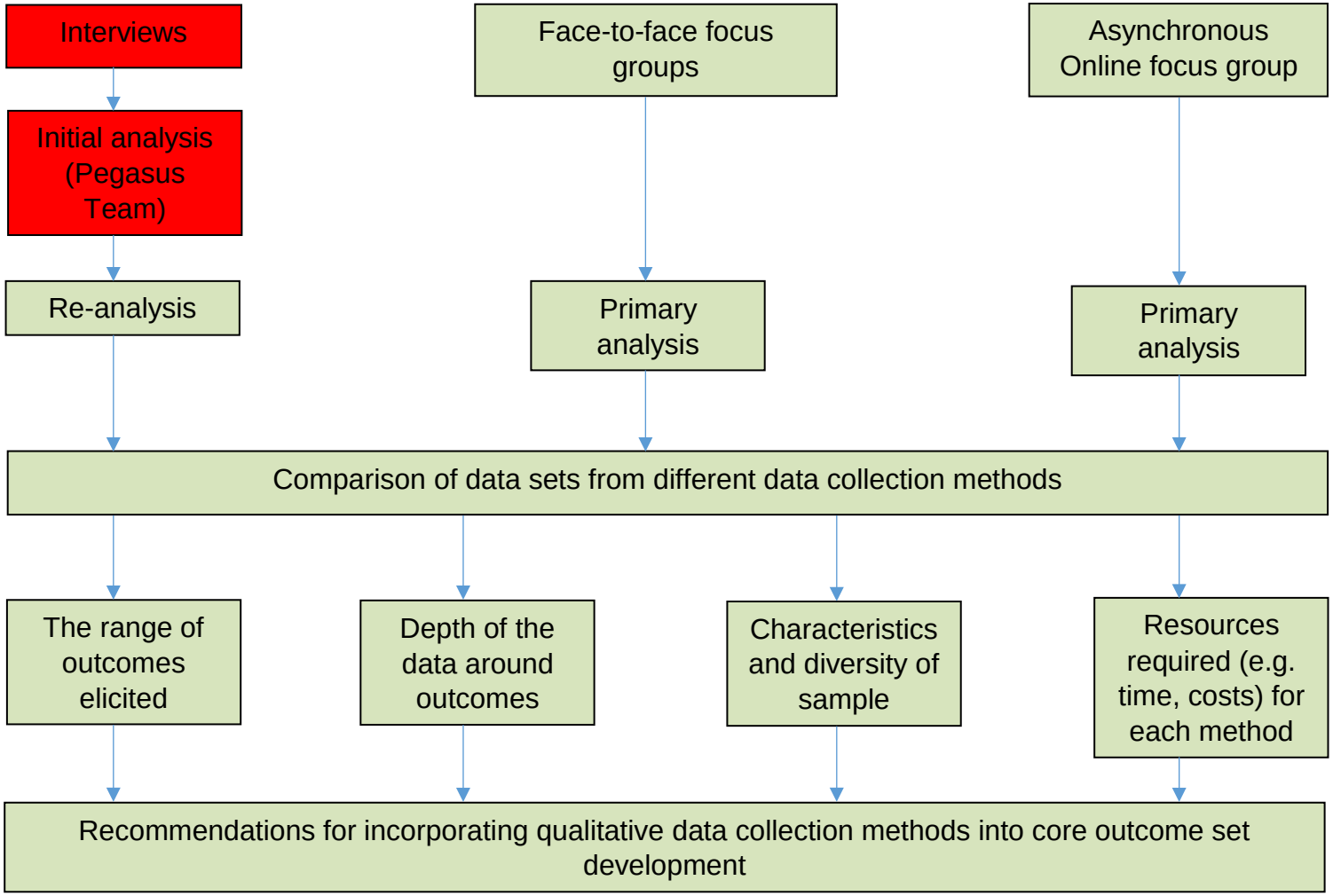
- Describe the range of outcomes elicited by patients via the different data collection methods;
- Compare the depth, richness, and understanding of the data in relation to outcomes important to patients;
- Identify the characteristics (including diversity) of the participants in each data collection method;
- Assess and compare the resources required to collect data using each data collection method.

Objectives:

- To undertake primary qualitative data collection by recruiting a maximum variation sample of participants;
- To carry out thematic analysis on the primary data to identify outcomes important to the participants;
- To carry out re-analysis of the interview data collected as part of the PEGASUS feasibility study to identify outcomes important to participants;
- To identify the similarities and differences between the outcomes identified by different data collection methods;
- To compare the depth of understanding and the richness of the data around the preferred outcomes identified by the different data collection methods;
- To compare recruitment rates and the diversity of the participants in each qualitative data collection methods to establish the feasibility of using qualitative methods as part of a COS development exercise;

- To assess the resources required to incorporate qualitative methods in a COS development exercise (in terms of researcher and participant time and the costs associated with data collection and analyses).

Figure 4.1 below outlines the study design of the OSCAR study.



Key: The PEGASUS study team completed the sections in red. This study completed the green sections

Figure 4.1 Study design of the OSCAR study

4.4.2. Methods

The data collection methods used in this study were face-to face focus groups and asynchronous online focus groups. Inclusion and exclusion criteria were the same as the Pegasus study to facilitate the comparison of data.

Inclusion criteria

1. Adult burn patients aged ≥16 years;
2. Patients who have received pressure garment therapy for at least 6 months;
3. Patients may have completed pressure garment therapy, but no longer than two years ago;
4. Good written and spoken English.

Exclusion criterion

1. Patients who have received pressure garment therapy for conditions other than burns.

4.4.2.1. Sampling

a. Face-to-face focus groups

To ensure a wide range of views and opinions, participants were recruited using a maximum variation sample including age, gender, ethnicity, type of burn, the severity of the burn, and time since the injury and length of time in pressure garments. Maximum variation sampling is a variant of purposive sampling aimed at recruiting a sample of participants who can provide a diversity of perspectives on the research question (88). The aim was to hold up to five face-to-face focus groups of between 5-8 participants in each. To date, the average number of focus groups with patients and carers in a COS development exercise is five with an average of eight participants in each (61, 86, 87, 183).

b. Asynchronous online focus groups

Based on the findings of the narrative review (Chapter 3) asynchronous online focus groups were selected for use. These were chosen because of the convenience they offer participants - who do not need to be online at the same time - and to provide a contrasting data collection method to that of the face-to-face focus groups. In theory there are no limits to the number of participants you can involve in an online asynchronous discussion (184); however, in practical terms, if the environment is to make participants feel comfortable enough to disclose valuable information, large numbers are not advisable (97). To enable a direct comparison with the face-to-face focus groups the target sample size for

the online asynchronous focus groups was between five and eight participants, in up to five groups.

4.4.2.2. Recruitment

a. Face-to-face focus groups

Participants were recruited through NHS trust clinics at: Queen Elizabeth Hospital (University Hospitals Birmingham NHS Trust); The Welsh Centre for Burns, Morriston Hospital (Abertawe Bro Morgannwg University Health Board); and Southmead Hospital (North Bristol NHS Trust). The chosen sites all took part in the Pegasus feasibility study but only Birmingham participants had taken part in the qualitative aspect of the study. It was therefore important to check that those patients recruited from Birmingham to an OSCAR study focus group had not taken part in a Pegasus interview. Initial contact with potential participants was made either face-to-face by the occupational therapist (OT) during a patient's clinic visit or the OT contacted potential participants by telephone from patient lists. After briefly discussing the study with the patient the OT asked all interested potential participants for their consent to pass their contact details to the researcher (Janet Jones) (Appendix 7). The researcher then contacted all potential participants via their preferred contact method, as indicated in the contact details form. The researcher explained the details of the study to the participant, answered any questions the participant had and checked the participant's eligibility. Next, the researcher posted or emailed an invitation letter and participant information leaflet (Appendix 8) to the participant. One week after

sending the information the researcher contacted the potential participants giving them a further opportunity to ask questions. If they were still interested in taking part in the focus groups, the researcher explained they would contact the participant again within the next few weeks with details of the focus group arrangements. If a potential participant was no longer interested, the researcher thanked them for their time and interest in the study. The researcher reminded participants via their preferred contact method, two days before the start of the focus group.

In order to build up a good relationship with the OTs and to ensure their buy-in to recruiting patients to the study I kept in regular contact with them. Nevertheless, recruitment to the face-to-face focus groups was slow and not as successful as hoped. In hindsight, different approaches or a combination of approaches may have been more successful. One alternative approach would be to obtain permissions for the researcher (Janet Jones) to be available in clinic to speak to potential participants in more detail after a brief outline of the study by the OT. Additionally the offer of an incentive may have helped to increase participation (185).

b. Asynchronous online focus groups

With the limited time and resources often available for core outcome set development, it was decided to assess the feasibility of recruiting participants to the online focus groups through online methods on the assumption it may be

quicker and cheaper. See chapter 6 section 6.3.2.4 for a discussion on the implications of this approach to the research.

An advert about the study and online focus groups was placed on appropriate websites and/or chatrooms such as: The Katie Piper Foundation (186) and Changing Faces (187) with interested parties asked to contact the research team directly (Appendix 9 is the online advert and Appendix 10 is the list of the burns organisations with websites approached). The researcher (Janet Jones) contacted all interested parties via their preferred contact method to thank them for their interest in the study and to provide them with details of the study (Appendix 11 is a copy of the online participant information sheet). Potential participants completed an online consent form and screening questionnaire to establish their eligibility (Appendix 12). By completing and submitting the online questionnaire, participants consented to the researcher using this data to: assess eligibility, to inform the study, and to take part in an online discussion group should they be eligible. If a participant was eligible to take part, the researcher sent an email advising the participant of their eligibility. The email also advised the participant that they would receive details of the online focus group within the next few weeks. If a potential participant was not eligible, the researcher sent an email to the participant advising them that they were not eligible and thanking them for their time and interest in the study. Close to the start of the online focus group, the researcher sent out details of the participant's anonymous user ID and password (created by the researcher). Also included in the email were details of the website URL (Appendix 13 is a screenshot of the website), information on the study

(Appendix 11), the focus group ground rules (Appendix 14), a welcome message (Appendix 15) and instructions on how to access the discussion forum (Appendix 16). All of this information was also available on the OSCAR study website. All participants received a reminder email two days before the start of a focus group. Participants were encouraged to contact the research team if they had any additional questions about the research or if they had any technical problems when logging into the website and discussion.

Recruitment to the online focus groups proved slow and difficult. To address this problem ethical approval to approach those who were initially interested in attending a face-to-face focus group but who found they were unable to due to personal commitments was sought and approval gained. Unfortunately, this approach was unsuccessful and in future, it may be more successful to recruit participants for the online focus groups using face-to-face approaches.

4.4.2.3. Data collection methods

a. Face-to-face focus groups

The researcher (Janet Jones) facilitated all the focus groups with the support of a co-facilitator who has experience of conducting focus groups and qualitative research with burns patients (lead supervisor/supervisor). At the start of each focus group, the purpose and aims of the group were explained and participants

were asked to complete a consent form (Appendix 17) and a background questionnaire (Appendix 18).

Post-it notes were left on the table for participants to write down any topics they thought were important but were not being discussed and these could be reviewed at the end of the focus group. However, none of the participants chose to write on the post-it notes, preferring instead to focus on the discussion only.

The focus groups commenced with an icebreaker question posed by the facilitator asking the participants to introduce themselves and to explain what motivated them to attend the focus group. The aims of the focus groups was to elicit participants' perspectives on the treatment they received, their experience of the treatment, and the impact of the injury and the treatment on their lives. The discussion centred around three areas: 1) the participants' experiences of wearing pressure garments, 2) what was most important for the participants to achieve from their pressure garment therapy, and 3) what participants thought researchers should be assessing in research on pressure garments. We displayed a visual guide to the discussion on the available whiteboards. In addition, as the group discussed different topics the facilitator or the co-facilitator wrote these on the whiteboard next to the appropriate section of the visual guide. See Figure 4.2 for an image of the whiteboard from face-to-face focus group 1. The topic guide is in Appendix 19 and the focus group visual guide is in Appendix 20.

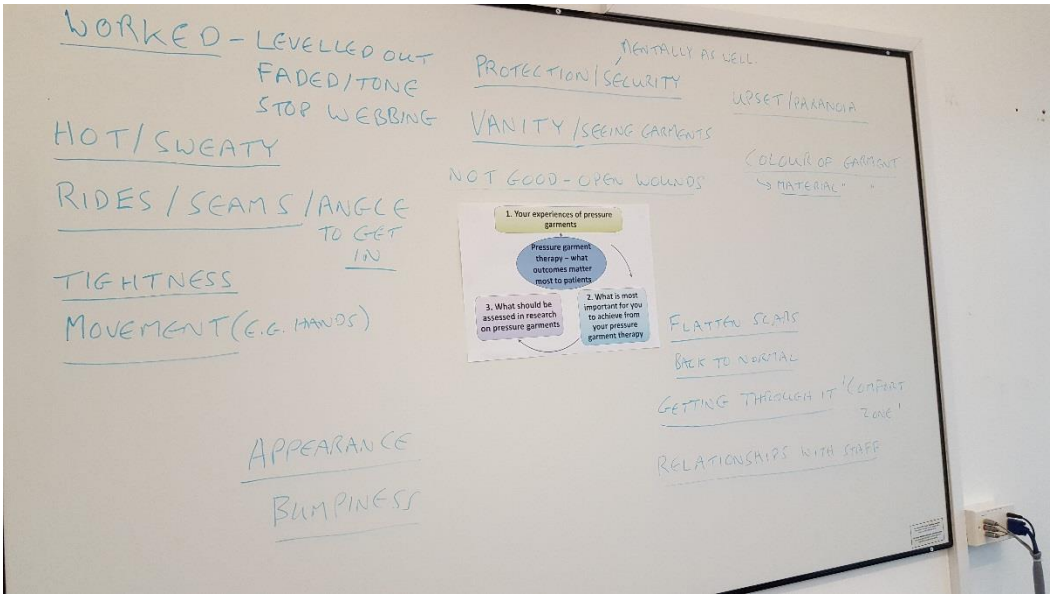


Figure 4.2 A view of the completed whiteboard from face-to-face focus group 1

b. Asynchronous online focus groups

The online discussion groups were conducted using WordPress (188) which was embedded into a purpose built project website, created by the researcher (Janet Jones) via Webhosting UK (189). Posted on the website was information about the study, a welcome message (Appendix 15) and ground rules for the conduct of the group (Appendix 14). All participants received a reminder of the ground rules at the commencement of the discussion. Participants received an anonymous user ID and password, created by the researcher, to use when accessing the site. The aim of the online focus group, as in the face-to-face focus groups, was to encourage participants to interact with each other as well as to respond to questions posed by the researcher. To facilitate comparison of the data collected from the face-to-face and the online groups the facilitator

asked the same types of questions (Appendix 21). The groups were open for 10 days. The facilitator (Janet Jones) logged into the site each day to summarise the previous day's posts and to ask a new question. Participants were encouraged to log in each day to comment and respond to any questions posed by the researcher or other participants and to contribute to the general discussion. The last two days of the groups were used for summing up the discussion and asking participants if they had any other related points they would like to raise.

c. Materials

The following materials (Table 4.2) were required to carry out the face-to-face and online focus groups:

Table 4.2 Materials required for face-to-face and online focus groups

Face-to-face focus groups	Asynchronous online focus groups
Venue	Website/hosting facility and access to internet connection
Digital audio recorder	Daily access to a computer
Focus group topic guide	Online focus group topic guide
Consent form	Online consent form
Participant information sheet	Online participant information sheet
Background questionnaire	Online background questionnaire
Whiteboard/Flipchart/paper/pens	Log in information for the discussion forum
Refreshments	Ability to save/download discussion thread (for analysis)

4.4.2.4. Data analysis

The purpose of data analysis is to interpret the data in relation to the research question(s), to make sense of participant accounts, to gain a deeper understanding or perception of the data and/or to use the data to develop a theory (88, 89, 190). There are many possible analytical approaches in qualitative research and often the chosen overarching methodology dictates the analytical approach (88, 89). The analytical approach taken in this study was thematic which is compatible with the interpretive description methodology (172, 173, 182).

Braun and Clarke recommend a six-step approach to conducting thematic analysis (191) these are outlined below in Table 4.3.

Table 4.3 The six stages of thematic analysis taken from Braun and Clarke (191)

Steps	Description
Familiarisation with the data	This includes transcribing the data, reading and re-reading the transcripts, noting initial ideas
Generating initial codes	Coding all interesting data throughout the dataset. Collating data for each code

Steps	Description
Searching for themes	Collating the codes into initial themes.
Defining and naming themes	Refining each theme and creating definitions and names for each one
Producing the report	Final analysis. Selection of extracts that tell the story. Reviewing selected abstracts to ensure they relate to the research questions. Produce final report.

Thematic analysis is atheoretical and can, therefore, be aligned to any qualitative methodology and is widely used by researchers (88, 89). Thematic analysis identifies themes and patterns across and within a dataset (88, 89, 191). Thematic analysis aligned well with the aim of this research to identify outcomes that are important to adult burns patients.

Data were analysed inductively with the following aims:

1) To identify and understand outcomes important to patients;

2) To assess the depth of the data explaining why the chosen outcomes are important;

3) To explore whether different data collection methods generate different data.

a. Re-analysis of PEGASUS interviews

Remaining blind to the outcomes of earlier work

My supervisors, as part of the PEGASUS research team, have a published paper reporting the qualitative results of the PEGASUS feasibility trial. Data from this trial were available throughout the duration of the Ph.D. and there was the possibility that the data could inform this research. Aware of this, the supervisors advised against reading the published paper, looking at the data, attending any meetings about the study and attending any presentations of the PEGASUS study results. This was to facilitate impartial independent conclusions about the data to be drawn.

The process of re-analysis

The interview transcripts were already transcribed and anonymised, they were uploaded into NVivo 11 (192). For this study, the interview data were re-analysed focusing on which outcomes were important to patients and to explore the depth of explanations around outcomes. The re-analysis of the PEGASUS data followed the process recommended by Braun and Clarke (Table 4.3.). To become familiar with the data the audio recordings were listened to and the transcripts were read and re-read several times. The PEGASUS interviews were the first dataset to be coded and analysed therefore it was agreed with the supervisory team that initially just a couple of interviews were to be coded by the researcher (Janet Jones) and then discussed with the team. Following this, the remaining interviews were coded and initial themes identified. Further discussion with the supervisory team helped to refine the codes and themes and these were

applied across all of the interviews. The final themes and codes were defined and checked for appropriateness to the research question.

b. Analysis of face-to-face focus group data

Data collection and exploratory analysis happened simultaneously thereby allowing the exploration of any interpreted themes in future focus group meetings by adapting the topic guide when necessary.

Face-to-face focus group data were audio-recorded, transcribed clean verbatim and anonymised by a specialist transcription company. Transcripts were anonymised and quality checked by the researcher (Janet Jones). To become familiar with the data the audio recordings were listened to several times and the transcripts were read and re-read several times and then uploaded into NVivo 11 (192). Initial codes were applied to all outcome-related data throughout the whole data set and these were subsequently discussed with the supervisory team prior to the further refinement of the codes. After refinement, the codes were sorted into initial themes these were then discussed with the supervisory team. Themes and their associated codes were finalised, checked for appropriateness and their relationship to the research questions.

c. *Analysis of online asynchronous focus group data*

Online focus group participants used researcher assigned pseudonyms therefore the transcripts were readily anonymised. The online discussion data were downloaded, converted into word documents, quality checked and uploaded into NVivo software (192). From here on the analysis follows the process outlined above for the face-to-face focus groups.

d. *Comparison of data sets*

Comparison of the three datasets enabled the identification of the similarities and differences between them. Collation of the separate datasets into one coding framework facilitated the comparison of the data across the datasets. It enabled inferences to be drawn in relation to objectives 3 and 4 of this thesis (Chapter 1 section 1.6.2): the range of outcomes elicited the depth of data around those outcomes, the characteristics of the sample and the required resources for each method.

Due to slipping timescales, and waiting to receive ethical and research and development approvals the interview dataset were coded and analysed prior to the commencement of the primary data collection. It is possible, therefore, that the analysis of the interview data and the knowledge gained from this may have influenced the primary data collection, analysis and interpretation. Prior knowledge of the interview findings may have led to the researcher (Janet

Jones) subconsciously seeking out particular outcomes from the face-to-face and online focus group participants.

4.4.2.5. Data saturation

Data saturation occurs when sufficient data are available so that the researcher can fully describe, explain and understand a phenomenon and further data collection does not reveal any new information (193-195). The achievement of data saturation is an informed yet subjective decision made by the individual researcher or research team. It should be noted that the amount of data collected does not necessarily equate to saturation; very detailed and in-depth data from fewer interviews or focus groups can achieve saturation (195). In this study, the interview dataset achieved saturation when no further outcomes arose after the coding of the majority of interviews.

4.4.2.6. Using qualitative data to define outcomes

The definition of and the recommended process for developing a COS is outlined in the Core outcomes measures for effectiveness trials (COMET) handbook (53) and is discussed in Chapter 1. An outcome domain is a broad classification of outcomes, which has associated outcomes mapped to it. Generally, the process of developing outcome domains and outcomes is as follows (16, 42, 196):

1. Create overarching domains (usually identified from a systematic review and existing literature);

2. Map each identified outcome to a domain.

However, it is to be noted that there are currently no recommended guidelines for COS developers on how best to execute this process (53, 67). The grouping of outcome domains and outcomes is specific to each research area and can be defined according to stakeholder groups, disease states, treatment and/or quality of life (77, 197, 198).

The COMET initiative does not recommend using qualitative methods alone to develop a COS, rather they should be used as part of a wider development process including systematic reviews, consensus exercises (often a Delphi) and a finalisation meeting (53). There is no existing guidance on the best methodology or methods to use when identifying outcomes from qualitative data; therefore, it is the decision of the research team to decide which analysis method is most suited to their study design and research question (53).

When writing up findings from a COS development exercise the COMET handbook recommends discussing how the findings add to existing knowledge, how methods have contributed to the COS development process and whether any new outcomes have been identified compared to those already known (53).

For the purposes of this research, the definition of an outcome is something that is important to patients and that is the consequence of a disease or of the

treatment of a disease. Outcomes from the OSCAR study data were identified through thematic analysis.

4.4.2.7. Duration of the study

The OSCAR study started in Aug 2016 and ended in October 2017. Data collection started in March 2017 and concluded in August 2017. The PEGASUS study interviews were undertaken between February and September 2015. The face-to-face focus groups took place during March and April 2017 and the online focus groups in June 2017 and August 2017.

4.4.2.8. Withdrawal from the study

Participants were advised that they had the right to withdraw from the study at any point, for any reason without prejudice to their future medical care and they did not have to give a reason for their withdrawal. If a participant withdrew after taking part in a focus group, it was not possible to exclude their data from the anonymised focus group transcript.

4.4.3. Ethics

The researcher (Janet Jones) ensured that the study was conducted in line with the principles of good clinical practice and conformed with: the Department of

Health Research Governance Framework, the Declaration of Helsinki and the University of Birmingham's Code of Practice for Research (199, 200).

The choice to include online focus groups as part of this research came with its own challenges relating to sponsorship and ethical approval relating, in the main, to the safeguarding of participants' anonymity in the online environment. Following discussions with the University of Birmingham legal and data protection departments, sponsorship of the study was dependent on meeting several conditions; the server of the chosen platform had to be in the UK, the website and the discussion forum needed to be user friendly, and closed to everyone other than the facilitator and those participants invited to take part. Finally, participants IDs were to be pseudonyms provided by the research team (so that identification by other participants and those who may inadvertently access the discussions would be less likely). This information may be pertinent for future researchers planning to use online qualitative data collection methods in the UK.

4.4.3.1. Research ethics committee

This research study received a favourable opinion from the Coventry and Warwickshire Research Ethics Committee and the Health Research Agency (HRA). Reference number for both: 16/WM/0307.

4.4.3.2. Research governance

The research and development approvals for the OSCAR study are outline below:

The Queen Elizabeth Hospital (University Hospitals Birmingham NHS Trusts) reference number RRK5853.

Southmead Hospital (North Bristol NHS Trust) reference number: 3860.

Morriston Hospital (Abertawe Bro Morgannwg University Health Board) reference number: 206685.

4.4.3.3. Informed consent

All focus group participants were required to provide informed consent. Face-to-face participants provided written informed consent before the commencement of the discussion. Online participants were required to complete an online consent form, designed and administered using Smartsurvey™ (201). See Appendices 12 and 17 for copies of the consent forms.

Retrospective consent was sought from the participants of the PEGASUS study for their interview data to be included in the Oscar study. This was required because the PEGASUS participants did not originally provide consent for their data to be used in other research studies. Retrospective consent was obtained by a member of the PEGASUS research team contacting each participant to ask permission for their interview data to be used in the OSCAR study.

4.4.3.4. Patient safety and wellbeing

Throughout this research study, it was important to ensure the safety and wellbeing of participants. This research used qualitative methods with burns patients and, although unlikely, it was possible due to the sensitive nature of the subject that participants may get upset during a focus group discussion. Therefore, it was important to have a plan, a distress pathway, in place to deal with such an incident. Depending on the circumstances, this included:

- Checking to ensure that the participant was okay and happy to continue.
- Signposting to relevant support services, or ensuring that the participant was able to access suitable support immediately.

An experienced co-facilitator (supervisor JM or LJ) was on hand to help make judgements about the most appropriate course of action, for example, taking a participant who was showing distress to one side or to a private location away from the focus group venue to assess the need for signposting to support services or immediate support. The facilitators had contact details of local burns support services. If a participant remained upset and did not wish to continue with the focus group, they were able to withdraw from the research.

The welcome screen of the website advised participants that they were able to contact the research team should they become upset or distressed during the online discussion and felt that they needed support. Participants could withdraw from the research and/or be advised to contact their usual care team or GP if

deemed necessary. The support of experienced facilitators (supervisors JM or LJ) was at hand to advise if it was judged that more urgent support was required (e.g. out of hours counselling or GP). To my knowledge, no participants in either the face-to-face or the online focus groups became distressed.

In addition, it was important that the facilitator and co-facilitator had a debrief session after the focus groups where they could discuss their views on the focus group and have the opportunity to discuss any upsetting incidents that may have arisen. Fortunately, there were no upsetting incidents in any of the focus groups.

4.4.3.5. Data protection and confidentiality

Data were collected and retained in accordance with the Data Protection Act 1998 (202) and good clinical practice guidelines (199, 203). Interview and face-to-face focus group audio recordings were securely stored on encrypted and password protected computers and networks at the University of Birmingham. All patient based data (paper and electronic records) were securely stored in locked cabinets and password protected computers and networks at the University of Birmingham. Data were marked with a unique study ID and all personal identifiers removed from hard copy interview transcripts. Data were only accessible by members of the research team.

4.4.3.6. Quality control and assurance

All members of the research team had received good clinical practice (GCP) training. The researcher was in regular contact with the local collaborators to ensure compliance with the protocol and to resolve any issues that may have arisen.

4.5. Resources

Objective 4 of this thesis was to provide information on resources in terms of costs and time required to carry out qualitative research as part of a COS development exercise. This information will help inform future COS developers about the resources required and the associated costs to help them to make an informed choice about which qualitative methods to choose.

To achieve objective 4 the following information were recorded on an excel spreadsheet:

- The dates of submission to regulatory authorities (REC, HRA, and R&D) and the date approval received;
- The date recruitment commenced in each hospital;
- The dates I contacted relevant websites to ask if they would advertise the online focus groups. Record of replies received from websites;
- All requests for online adverts and tweets to be re-posted;
- The number of telephone calls and/or emails needed to contact potential participants and organise focus group dates;

- Costs associated with setting up and running the focus groups, building the study website and researcher time;
- Costs associated with the above activities.

See Chapter 5 section 5.3.4.4 for details of the assessment of resources required when using qualitative research as part of a COS development.

4.6. Reflexivity

Qualitative data are a product of the relationship between researcher and participant(s) (204). Dependent on the topic, a researcher can be regarded as an "insider researcher" where the researcher shares some aspects of the participants' identity such as gender, or an "outsider researcher" where the researcher does not share any commonalities with the participants, for example, a female researcher whose participants are all male (88, 205). Although in truth, researchers may be a combination of both (205). For example, my own stance in this research project is as an insider and outsider researcher. I am an insider because I can relate to some of the issues faced by burns patients, such as the appearance of the skin and itchiness, but I am also an outsider because I have not experienced a burn injury. This may influence my data collection from the point of view that I am able to empathise with the participants in relation to itch and scar appearance. However, not having suffered a burn injury I hoped to be able to view the data as objectively as possible. A brief biography is in Appendix 22.

In qualitative research, researchers practice reflexivity by critically reviewing their own role in the research process including their beliefs, knowledge, experiences, and their influence on the research process itself (88, 89, 205-207). Reflexivity does not just relate to data collection but to the whole research process, which can include keeping reflexive accounts (diaries) throughout the process (88, 89, 205-208). Practising reflexivity can help the researcher to recognise and reflect on potential biases and how their prior knowledge may affect the research (206, 207). Following each focus group, I made notes on my thoughts, ideas, and impressions of the discussion. (Appendix 23 is an example of a reflective note). On a personal level, I felt that I could understand and relate to the emotional and symptomatic experiences described by the participants and I was fully aware it was possible that I may prioritise these and have a tendency to focus on them in the focus group discussions and analysis. However, by having my supervisors as co-facilitators, following the topic guide, practising empathic neutrality, trying to avoid bias and to be neutral in data collection, interpretation and presentation of the data I hoped to remain as impartial as possible (89). Additionally, reflecting on my performance helped me to focus on all of the topics arising in the focus groups as did discussing with my supervisors my approach and progress with the analysis (section 4.4.2.4). These discussions helped me to focus on the complete datasets and all of the interpreted topics.

4.7. Summary

This chapter has provided details about the chosen methodology and methods for this research study. It has outlined and justified my generic qualitative approach, which aligns with the purpose of this study. An explanation of the choice of data collection methods (face-to-face and online focus groups) was included as was a summary of the measures put in place to safeguard the participants and the researchers. Recruitment to the online focus groups was particularly challenging and the strategy adopted to try to address was discussed. A brief discussion on identifying outcomes through qualitative research approaches was also included.

CHAPTER 5: WHAT OUTCOMES ARE IMPORTANT TO ADULT BURNS PATIENTS THAT HAVE EXPERIENCED SCAR MANAGEMENT THERAPY? INSIGHTS FROM DIFFERENT QUALITATIVE DATA COLLECTION METHODS

5.1. Introduction

This chapter reports the re-analysis of the PEGASUS study interviews (See Chapter 4 for details of the PEGASUS study) and compares these data to the primary data collected through face-to-face focus groups and online asynchronous focus groups undertaken as part of the OSCAR study. Following an initial descriptive summary of each of the three datasets, the synthesised results are described in relation to objectives 3 and 4 of this thesis on 1) the range of outcomes elicited, 2) the sample characteristics, 3) the depth of data collected, and 4) the resources required to carry out qualitative research. (Chapter 1, section 1.6.2. provides a complete list of objectives).

5.2. Methods

Chapter 4 section 4.4.2.4 provided detailed information on the methods used to re-analyse the PEGASUS study interviews and to analyse the primary collected data (the OSCAR study). In brief, for the OSCAR study, OT staff from NHS burns units identified potential participants for the face-to-face focus groups. Social media and burns websites were used to facilitate recruitment of participants for the online focus groups. Data were analysed thematically to identify outcomes that are important to adult burns patients.

5.3. Results

The OTs referred twenty-six eligible patients for the face-to-face focus groups. Of these five were not interested in taking part when further details were provided, the researcher was unable to contact two of the potential participants, five were unable to make any of the focus group dates and times and three dropped out on the day of the focus group. Twenty-one people expressed an interest in taking part in an online focus group. Following screening two were not eligible to take part; two were not interested after receiving more details about the study; the researcher was unable to contact eleven of the potential participants; and one person never logged into the study. It was judged that saturation in the face-to-face or online focus group datasets was not achieved but was in the interviews dataset (see chapter 6 section 6.7 for a discussion on the implications of this).

5.3.1. Study population and duration

Twenty-four adult burns patients participated in the PEGASUS interviews. In total, 11 participants attended the face-to-face focus groups; two focus groups with four participants and one group with three. Five participants took part in two online focus groups, with three in one and two in the other. Socioeconomic status data (educational level and employment status) were not available for the interview participants. Due to the lack of these data, it was not possible to make meaningful comparisons. Participant characteristics are summarised in Table 5.1 On average, the interviews lasted 51 minutes (range 23 to 108 minutes), the

face-to-face focus groups 109 minutes (range 101 to 125 minutes) and the asynchronous online groups 10 days.

Table 5.1 Summary of participant characteristics

	PEGASUS Interviews n = 24 participants	OSCAR Face-to-face focus groups n = 11 participants	OSCAR Online focus group n = 5 participants
	n (%)	n (%)	n (%)
Gender			
Male	18 (75)	5 (45)	1 (20)
Female	6 (25)	6 (55)	4 (80)
Age (years)			
<20	1 (4)	0 (0)	0 (0)
21-30	4 (17)	1 (9)	2 (40)
31-40	1 (4)	2 (18)	1 (20)
41-50	6 (25)	2 (18)	0 (0)
51-60	6 (25)	2 (18)	1 (20)
61+	6 (25)	4 (37)	0 (0)
Not stated	0 (0)	0 (0)	1 (20)
Ethnicity			
White	20 (84)	11 (100)	5 (100)
Black/African/Caribbean/Black British	2 (8)	0 (0)	0 (0)
Black Pakistani	1 (4)	0 (0)	0 (0)
Black Asian	1 (4)	0 (0)	0 (0)
Type of burn			
Flame	13 (55)	5 (45)	1 (20)
Scald	7 (29)	4 (37)	1 (20)
Chemical	0 (0)	0 (0)	2 (40)
Contact	2 (8)	0 (0)	1 (20)
Friction	1 (4)	0 (0)	0 (0)
Electrical	1 (4)	2 (18)	0 (0)
Percentage total burn surface area			
<10	6 (25)	1 (9)	3 (60)
10-20	0 (0)	1 (9)	1 (20)
21-30	4 (17)	4 (36)	0 (0)
31-40	0	0	0 (0)
41-50	2 (8)	0	0 (0)
>50	4 (17)	1 (9)	0 (0)
Unsure	8 (33)	4 (36)	1 (20)

5.3.2. Outcome domains identified

Thirty-three outcomes that are important to adult burns patients were interpreted across the three datasets. The outcomes were grouped into six outcome domains: 1) scar features; 2) scar sensation; 3) mobility, movement, and function; 4) psychological well-being; 5) returning to a normal life, and 6) treatment regime. Table 5.2 briefly describes each of the domains informed by participants' descriptions. Table 5.3 summarises the outcome domains and the associated outcomes that were interpreted across all three datasets. See Appendix 24 for the codebook with descriptions of all of the outcomes.

Table 5.2 Descriptions of the outcome domains

Outcome domain	Description
Scar features	How participants described the appearance of their scars, for example, colour and height. What Participants' hoped treatment could achieve. Participants' perceived success or failure of the treatment.
Scar sensation	How participants described how their scars felt, such as itchiness and pain. What participants' hoped the treatment of these symptoms could achieve. Participants' perceived success or failure of the treatment.
Mobility, movement, and function	Participants' mobility (ability to walk), their range of movement in the affected area and their function (ability to carry out everyday activities and tasks).

Outcome domain	Description
Psychological well-being	The emotional and mental effects following a burns injury.
Returning to a normal life	The things participants described as important for them to feel a sense of normality. The difficulties faced by participants to accept what has happened and move on.
Treatment regime	The burden of treatment including coping with multiple treatments and/or other medical conditions as described by the participants.

Table 5.3 Outcomes within each domain across all datasets (see codebook presented in Appendix 24 for a detailed description of each outcome)

Scar features	Scar sensation	Mobility, movement, and function	Psychological well-being	Returning to a normal life	Treatment regime
Colour	Itchiness	Function	Anger	Getting out and about	Daily routine
Dry, cracked skin	Lack of feeling	Mobility	Depression	Driving	Feeling like a burden
General appearance	Pain	Range of movement	Fear	Hobbies and pastimes	Frequent appointments
Height and thickness	Sensitivity		Loss of identity	Acceptance	Lots to deal with
	Discomfort		Guilt	Returning to work or education	Recovery time
			Protection and security		
			Self-confidence		
			Stress		
			Support network		
			Trauma		
			Vulnerability		

Outcomes are rarely independent of each other. For example, dry cracked skin is also associated with itchiness. When discussed in the following narrative, outcomes will be italicised in the corresponding colour of their domain (colours are shown in Table 5.3), e.g. ***Dry cracked skin*** *(scar features)***.** This is to make it easier for the reader to identify the links between outcomes and domains.

The following sections describe the outcomes identified and interpreted from each of the three data sets. First, there are descriptions of the findings from each dataset in relation to the outcomes presented in Table 5.3. Secondly, the data are described against the four comparison criteria outlined in Chapter 4 section 4.4.1. Throughout this chapter, quotations are used to illustrate the richness of the dataset for the reader. Each quote has an identifier allocated to it indicating whether the quote comes from an interview, face-to-face focus group or an online focus group.

5.3.3. Descriptive summary of findings

The findings for each of the outcome domains across the three datasets are described below.

5.3.3.1. Scar features

In this domain, participants described the look of their scar and their hopes and perceived success/failure of treatment in relation to these attributes. Participants across all datasets talked about the features of their scars using several different terms. Table 5.4 provides examples of the terminology used.

Table 5.4 Summary of participant terminology

Outcome	Participant descriptions
Colour	Red, pink, purple, inflamed
Dry, cracked skin	Dry, cracked, wrinkled
Height and thickness	Raised, lumpy, bumpy, thick
General appearance	The overall appearance of the burn site. For example, wanting it to look *normal*, "you want to look as good as you can possibly get" (Interview; participant CA04)

Improving these features was important to the participants although some acknowledged that a return to *"normal"* looking skin would take a long time, even years:

> *"Redness normally takes time like they say as scars heal. It's like me cheek they're quite red now compared to my complexion, but it's like my OT said to me that will take time anyway, talking 18 months, two years' time"* (Focus Group 2; participant 4)

The majority of participants talked about wanting the ***colour*** *(Scar features)* of the scar to fade but in the following quote, the participant is also trying to make sense of why the ***colour*** of their scar changed depending on the time of day. In response to a question about the benefits of pressure garments this reply may indicate that not only is the fading of the ***colour*** important to the patient but also that understanding of why it reacts the way that it does is important in order to have some control over the situation:

> *"When I wake up the condition of the scar is better than say towards the end of the day the scar is actually redder, the inflammation, I suppose the body continues to produce inflammation, and so after a nice rest the condition is better"* (Interview; participant EG01)

The ***general appearance*** *(Scar features)* of the scar rather than individual features were discussed in many different contexts including how it can change as time and treatments progress. To some, where the scar was located on the body dictated how important the appearance was which, in turn, could affect an individual's ***self-confidence*** *(Psychological well-being).* In instances where a scar was visible participants talked about trying to hide or camouflage their scars when out in public:

> *"I have consciously avoided short-sleeved tops and always wear trousers but when I have worn a skirt I am aware of hiding the scar"* (Online focus group 2; participant 1)

In the main, participants felt that treatments, (pressure garments, massage, and creaming, laser treatment) helped to reduce ***redness***, ***dryness*** and the ***height***

and thickness *(Scar features)* of the scars. However, there were those who thought that treatment had either been ineffective, not as effective as they had hoped or they were unsure whether it was the treatment or a combination of things that had helped their recovery:

> *"I don't know whether the pressure garments were helping to flatten any scars or helping my hand in that way, because you can't tell when you're a patient is it the massage, is it the stretching, is it the creaming, or is it the pressure garment, it may or may not, I don't know"* (Focus Group 3; participant 3)

5.3.3.2. Scar sensation

This domain describes how the scar felt to the participants. Often the features of the scar are linked to the sensations of the scar ***pain***, ***itchiness, lack of feeling***, ***sensitivity,*** **and** ***discomfort*** *(Scar sensation)*. For example, the ***colour*** *(Scar features)* of the scar could be perceived as having a direct influence on ***itchiness*** *(Scar sensation)*. Participants talked about the ***pain*** *(Scar sensation)* they experienced at the site of the scar and for some, this was exacerbated by pain from an existing medical condition, which may have affected their treatment regime and quality of life:

> *"I have another medical condition which means that I'm home, and I'm having to control pain for that, so to have another area with pain was very difficult"* (Interview; participant EG02)

A scar can be intensely itchy which may have a debilitating effect on participants' lives. A few talked about how they changed to wearing cotton clothing in an

attempt to reduce the ***itchiness*** *(Scar sensation)* and many talked about how heat exacerbated it. Participants understood that scratching made things worse but trying not to scratch proved to be challenging for some. In general, it was accepted that ***itchiness*** *(Scar sensation)* was part of the healing process and participants found that it eased as healing progressed. They discussed how the treatments themselves could make them feel itchy:

> *"Bad points are that they (pressure garments) can be very itchy in hot weather and I started to get heat rash and I run regularly so ended up, in the latter period of wearing, taking them off whilst running"* (Online focus group 2; participant 1)

Participants reported a ***lack of feeling*** *(Scar sensation)* at the injury site and these sensations often affected touch and ***function***ality *(Mobility, movement, and function).* For example, one participant explained how everything he touched felt like sandpaper, whilst another described how he could no longer feel anything at the tips of his fingers:

> "*I still can't feel the tips of my fingers anyway, that's gone. I can take a pin and put that in my fingers, I just don't feel a thing, so I've got to be careful, especially I could cut my finger and not even know about it. So those are the sensations which I've still…" (*Focus Group 3; participant 2)

As with the features of the scar, some participants felt that treatments helped to reduce the sensations they were feeling at the site of the scar:

> *"from the pain aspect, because I guess all the time it's raised as I was being explained to, all the time it's raised, and that's causing the itching and the sensitivity, and all that, so all the time the pressure garment is on it that's pushing it down, and that's helping with the pain and the itching".(*Interview; participant EG02)

However, the following participant described how the regaining of feeling resulted in an increase in **sensitivity** *(Scar sensation):*

> *"When it did come back I'm thinking I don't know whether I wish to have this now, because of the feeling in my arms is worse now than before. It's a lot more sensitive".* (Focus Group 1 participant 1)

Participants also talked about the **discomfort** *(Psychological well-being)* they felt at the site of the scar:

> *I also have a bit of scar tissue in my lip that still causes me some discomfort. I feel I cannot open my mouth as wide as I used to, or turn my head to the side very far.* (Online Focus Group 1; participant 3)

5.3.3.3. Mobility, movement, and function

Participants used the terms ***mobility, movement and function*** interchangeably. The following definitions apply for the purposes of this analysis: 1) mobility - the ability to walk, 2) movement - the range of movement in the joints, and 3) function - the ability to carry out everyday activities and tasks.

The features and sensations of a burn injury can have a direct influence on ***movement*** and ***function*** and this, in turn, can affect a perceived return to a ***normal life*** *(Returning to a normal life).* Having ***Mobility, function*** and a full ***range of movement*** *(Mobility, movement, and function)* were important to participants and in some cases, it was more important than the ***appearance*** *(Scar features)* of the scar.

> *"For me it was all to do with mobility, that's how I felt why I think I went for it more than anything, I wanted the mobility"* (Interview; participant CA05)

However, this was not always the case and the location of the injury and the participants' subjective views on the appearance of their scar often determined their priorities. For example, those with good ***function*** and ***mobility*** *(Mobility, movement, and function)* wished for the ***appearance*** *(Scar features)* to be improved. Nevertheless, as described by one of the online participants it may not be as straightforward as this implies. For some, an improvement in both outcomes was desirable:

> *"I think this is a tough one because both appearance and regaining original movement are two big outcomes. At the end of the day, I would be unhappy if my burn looked awful but didn't restrict movement, and I'd also be unhappy if the burn looked good but caused restricted movement".* (Online Focus Group 2; participant 1)

Some participants talked about the importance of regaining their ***mobility*** post-injury and how initially they needed aides such as crutches or walking sticks to help them. Similarly regaining the ***range of movement*** *(Mobility, movement, and function)* they were used to or would be happy with was also important:

> *"That's like me, I'm just stretching it now. Every morning I wake up if they're stuck like that I have to… it's like breaking a slab of ice, just to crack your arms back open, and then that's when you feel I've just done this for three/four weeks solid now, every morning stretched, but how much longer is it going to go on for? How much longer am I going to have to go and crack my arms again just to make them feel normal".* (Focus Group 2; participant 4)

A limited ***range of movement*** *(Mobility, movement, and function)* can have a direct effect on the ability to carry out everyday tasks. Functional ability can help to make participants feel that they are ***moving on*** and ***returning to a normal life*** *(Returning to a normal life)*; however, a lack of ***function*** *(Mobility, movement, and function)* can greatly diminish their quality of life and they may need to rely on others for a while:

> *"Yes, and I couldn't wear shoes with laces, because I couldn't bend down. So I'd actually for the winter of 2013 and spring of 2014 I didn't go out very much, because I had no... I couldn't put any clothes on, any socks or proper shoes on to brave the elements. Okay when I had somebody else to help me, my family, but during the week there was no one around".* (Interview; participant EG01)

Regaining ***function*** *(Mobility, movement, and function)* may not always be a participants' initial concern. The following quote by an online participant described how regaining ***function*** was not the primary aim at first not losing a limb was understandably the main priority:

> *"As for overall treatment, I guess it changed as initially I just didn't want to lose my arm but overall I just wanted to be as back to normal as I could be. At least on a practical level I wanted to get function back".* (Online Focus Group 1; participant 2)

Some participants talked about how they made changes to their life in order to assist their recovery. Sometimes these were major changes made to their homes to assist with their ***mobility*** and ***function*** *(Mobility, movement, and function)* such as installing a stair rail or a walk-in shower. However, not all

adjustments made by the participants were major sometimes the changes were temporary:

> *"At first while still recovering, I had a foam tube that fit over a spoon or fork, so that the handle was larger and easier to hold. By the time I entered university, I was able to eat without it".* (Online Focus Group 1; participant 3)

Many viewed exercise as the key, alongside treatment, to regaining ***mobility***, ***movement and function*** and some were keen to expedite this aspect of their recovery:

> *"Whenever I was not reading, just doing basic physio exercises on my hand, trying to get feeling, get movement, and get life back in them. It really was amazing how quickly they started to move and how soon I got things working back to their normal selves, which is nice".* (Interview; participant QA08)

Some participants associated improvement in ***range of movement*** and ***function*** *(Mobility, movement, and function)* with a reduction in the ***height and thickness*** *(Scar features)* of the scars. Whilst pressure garments are designed to reduce the ***height and thickness*** *(Scar features)* of scars, participants also reported that pressure garments provided support whilst they exercised in a similar way to supports used in sports:

> *"I thought they were very good, not only did they help reduce the swelling, definitely smoothing out the scars, and also providing the support on where I've lost all the muscle and the strength in the tendons and stuff, it gives you that bit of extra support so that you can move". (*Interview; participant EG06)

5.3.3.4. Psychological well-being

A burn injury may have a significant effect on the psychological well-being of a patient. Overall, the majority of the psychological symptoms raised across the datasets were negative feelings or emotions such as a ***loss of identity*** *(Psychological well-being)* or ***guilt*** *(Psychological well-being)* because they are **feeling like a *burden*** *(Treatment regime)* to others following their burn injury. ***Fear*** *(Psychological well-being)* that the same may happen again to themselves or to loved ones manifested itself as a worry and the participants talked about deliberately avoiding activities that may result in a similar type of accident:

> *"My burn was from a flame, that basically erupted out of nowhere over a grill where I was working. It was very difficult for me to cook or do anything like that, as I would constantly fear, for example, the toaster would spontaneously combust while I was near it. Being at university, I did all I could to avoid using the toaster or strategizing so that I would not be near it, but as time has gone on, I have progressed. I am able to cook in a toaster or microwave, and even an oven or electric stove with some caution. Gas stoves and grills I avoid, and the thought of attending a bonfire or hibachi dinner repulses me".* (Online Focus Group 1; participant 3)

A few participants explained their **guilt** *(Psychological well-being)* about having to rely on relatives to help with treatments and visits to the hospital and the inconvenience this may place on them:

> *"I felt guilty because I knew I was going to be burdening my grandparents with this. My parents having emigrated back to South Africa were completely out of range, it would have taken them a day just to get here, and that was one thing that worried, my mother was threatening to come over, because her son has got injured, she wants to be here".* (Interview; participant QA08)

In face-to-face focus group 2, participants discussed a **loss of identity** *(Psychological well-being)* and the feeling that a burn injury determines who they are now. Each time a participant met with their usual social group (family, friends) it seemed as though the only thing they were interested in was asking the participant about the injury. This aspect was particularly upsetting for participants because in the main it came from friends and family:

> *P3 "You feel like telling your own family to go away".*
>
> *P2 "It's almost since that's happened that's just you know, you're like oh yeah you're the one that had the seizure and melted half your arm off, and that's annoying. It's like if you haven't seen them for a while and then that's all they ask you about and you're like…"*
>
> *P1 "I get that with my family as well".*
>
> *P2 "Yeah, it's quite annoying isn't it?"*
>
> (Focus Group 2; participants 1, 2 and 3)

A few participants talked about losing their "official" identity through the loss of personal documents (passport, driving licence, qualification certificates) in a fire, for example:

> *"No, because well obviously my passport photograph didn't look nothing like me, and also... my passport didn't look like me and I had no identity because everything in the fire, every qualification, every nice bit of clothes, my daughter's pictures, my computers with all my pictures on, everything was gone, kaput".* (Interview; participant QA01)

There was a link between ***vulnerability*** *(Psychological well-being)* and a participants' view of the **appearance** of their scars, this was in the main highlighted by those whose scars were visible. They described how they felt stigmatised and alone for having a burn injury, how they were susceptible to stares and comments from others, and how this made them feel:

> *"I have received some really horrible comments about my mask. The first day I wore it in public I got called disgusting and my already knocked confidence took another beating. Since then I have had to deal with pointing and laughing, being told to take my mask off because it's not Halloween, being asked what I am dressed up as and being told I look ridiculous among other things. One of the things I really hate is when complete strangers come up to me, point at my face and say 'what have you done to your face?' That really bothers me".* (Online Focus Group 1; participant 1)

The above quote relates to the visibility of burns and pressure garments and how participants would prefer to hide their scars and pressure garments in public in order to avoid comments and stares. However, one participant in the face-to-face focus groups explained how she thought having a "hidden" injury (one that is not immediately visible, i.e. on the torso) can be just as frustrating because people may not realise what you are going through and what your daily life is like:

> *"I suppose I was lucky with mine, no one could see. But then sometimes that was hard because I thought you don't know what I'm going through, so it was worse in that way as well, even though I'm glad, but it's weird".* (Focus Group 1; participant 2)

Comments and stares damaged the ***self-confidence*** *(Psychological well-being)* of some of the participants. As one participant explained, **getting out and about** *(Returning to a normal life)* challenged their confidence:

> *"I was on the train here actually and it was absolutely packed and I just saw this girl staring it for ages, and then I caught her, well she looked up at me and I'm just there yes it's a scar, just stop it. It makes me feel more uncomfortable when people look at it, because they look at it oh what the hell is that?"* (Focus Group 2; participant 2)

Another described how the **stress** *(Psychological well-being)* of anticipating comments and stares from the public damaged their **self-confidence,** *(Psychological well-being)* making them feel vulnerable and paranoid about going out:

> *"I also hate it when people are staring at you, and specifically at the parts of you where you are burnt so you know you're not being paranoid. It makes me feel on edge that 1) what are they thinking and also 2) are they going to ask me and if so what do I say?"* (Online Focus Group 1; participant 2)

One of the online participants reported feeling traumatised by the accident and the resulting injuries but they believed that psychological counselling helped them to overcome the ***trauma*** *(Psychological well-being)*. Similarly, a participant in one of the face-to-face focus groups received a diagnosis of post-traumatic stress disorder (PTSD). Both described how pressure garments provided them with ***protection and security*** *(Psychological well-being):*

> *"I felt protected by them (pressure garments) as the accident left me quite traumatised (I did have several sessions with the psychologist)".* (Online Focus Group 2; participant 1)

> *"Something similar with what you said the comfort of it, because what I went through I also got post-traumatic stress disorder from it all".* (Focus Group 3; participant 2)

In addition to providing a sense of security, participants talked about how pressure garments provided protection from further injury and/or protection from their clothes, which can rub against the scar. The participants appreciated this perceived additional benefit of pressure garments:

> *"But it protected my skin from my clothes really. My clothes seemed like cardboard, like sandpaper, everything seemed so sore, rough against my skin. My skin was like baby skin"* (Interview; participant CA07)

> *"I found eventually after a couple of months of using that's security from… and I didn't know I was getting security from them, when I look back I must have done. It must have settled me a lot more mentally, I remember I wouldn't go out without it"* (Focus Group1; participant 3)

Some participants talked about suffering from ***depression*** *(Psychological well-being)* since the accident and the mental strain caused by thinking about what had happened, what the future may hold, and for some, this could manifest itself in suicidal thoughts:

> *"I was horrified, miserable, horribly depressed and just thinking God get me out of here" (Interview; participant EG08)*

> *"I didn't know what my face was going to look like, what it was going to finish up as, and I told them to put me down to be honest, I don't mind admitting it".* (Focus Group 1; participant 4)

A few of the participants talked about their ***anger*** *(Psychological well-being)* and frustration. This could manifest itself as anger at the burn injury or the treatment but the participants were confident that these types of feelings would subside as their recovery continued:

> *"I definitely think I have become more angry since wearing it but I hope that, once I no longer have to wear it, I will feel better".* (Online focus Group 1; participant 1)

Overall, when coping with any psychological problem participants agreed that it was important to have a good ***support network*** *(Psychological well-being).* This did not necessarily need to be professional and/or counselling support because participants viewed support from friends, family, and colleagues as equally valuable:

> *"I think I felt comfortable with them because they worked at the refinery, they knew I had the accident, and they supported me from a workgroup, the actual workers supported me while I had the accident".* (Interview; participant CA09)

5.3.3.5. Returning to a normal life

Returning to a normal life was important to the majority of participants. What constituted a return to normal varied by participant as did the extent to which they believed they could achieve it. Linked to this domain are ***scar features***, ***scar sensation***, **mobility, movement & function,** and ***psychological wellbeing.*** This is because without improvement in these domains it may be

difficult for a participant to accept that they are able to lead a life as close to their pre-accident life as they would like. The ability to get active, ***get out and about*** *(Returning to a normal life)* and to resume their ***hobbies and pastimes*** *(Returning to a normal life)* was very important to a large proportion of the participants. For example, the resumption of **driving** *(Returning to a normal life)* again following the accident and the resumption of favourite pastimes represented a regaining of independence:

> *"I needed to get back to driving because that way I could be independent and not need anybody else to go and do all my shopping and do everything for me, because I live alone"* (Focus Group 3; participant 4)

However, as suggested by one participant it is not always simple to resume a hobby or pastime even when you are physically able to do so. There can be psychological barriers to overcome too:

P4:	*"I just think that going back to swimming would be wonderful but I chicken out every time I think I ought to go and try it. I don't know why I'm so worried about it, but I used to swim three times a week and do a mile a week really, but I can't do it anymore, I can't bring myself to do it".*
Facilitator:	*"What is it that's stopping you?"*
P4:	*"I don't know".*
Facilitator:	*"Is it the appearance or…"*
P4:	*"No, because the appearance doesn't really bother me, I'm not really bothered about appearance, and I've tried my costumes on and they look alright. But with it being my feet mainly anyway no I don't know what it is, it just seems one last thing to struggle with at the moment, I can just leave it at the moment. Maybe I'll come round to doing it eventually."* (Focus Group 3; participant 4)

The majority of participants understood that it was possible things would never return to exactly as they were before and that it was important to accept this and to move on with life. The process of ***acceptance*** *(Returning to a normal life)* varied between participants. It may require learning to accept the appearance of the scar and accepting that they may be in pain for a long time. A participant in face-to-face focus group 3 viewed acceptance as threefold, acceptance of the accident, acceptance of the treatment process and acceptance of post-injury limitations:

> *"Accepting the processes, the treatments… I think there are three aspects to acceptance, accepting the limitations because you are limited in what you can do for a time"* (Focus Group 3; participant 3).

There were, however, other aspects related to ***acceptance*** *(Returning to a normal life)* and moving on which were also identified by the participants. These included willpower, realising how far you have come since the accident and having time to adjust to your new circumstances:

> *"Yeah, take everything a little bit at a time, don't go trying to run before you can walk type of thing"* (Focus Group 3; participant 2)

Returning to work or education *(Returning to a normal life),* had a positive influence on **acceptance** and **returning to a normal life.** Unfortunately, for many of the participants, this had not been straightforward because there were obstacles in the way. Other outcomes identified in this thesis can also hinder **returning to work or education** *(Returning to a normal life)*. For example,

participants may struggle to complete their ***treatment regime*** whilst working, or they may find any restricted ***movement*** *(Mobility, movement, and function)* may hinder physical aspects of a job, or an individual may not feel psychologically ready or able to return to work. By far the most talked about aspect of ***returning to work or education*** *(Returning to a normal life)* in the interviews and face-to-face focus groups was the lack of employer support and understanding:

> *"But it's not until something like this happens that you realise basically they [the employer] don't really care, they see you as everybody else so just they're not there for emotions and feelings you're just a number really"* (Interview; participant CA09).

Interestingly, the online groups suggested that how you feel does not always equate to how well your scars are healing. For example, just because a participant's scars are healing well does not necessarily mean that they feel capable of **acceptance** *(Returning to a normal life)*:

> *"I am continually asked how I feel about the scars as it is about how I feel as well as how they are healing from an expert's point of view and sometimes they are not aligned".* (Online Focus Group 2; participant 1)

Recovery time *(Treatment regime)* provided much needed space for some to consider their future and ***returning to work or education*** *(Returning to a normal life).* One participant described making a substantial change in their life by returning to education to fulfill a lifetime ambition:

> *"My priorities changed with it all really, because of the accident which I had and because of the support the steelworks has given me, well lack of I should say, my original goal was trying to get back to my*

original life, but that changed and I found it's a different life, so watercolours I do a lot of, was doing a lot of artwork at the beginning of the year, it was just something I sat down… I hadn't picked up a pencil for years. I left school at 16 and I had an option to go to the steelworks and get a craft ship or with a scholarship to [Name] Art degree or pay for everything, and I had the choice which way to go. My father said, "Go and get a craft, they can never take that from you, you can still study your art." So I never picked a pencil up from that time. So when I picked up a pencil again and started working with it I found it relaxing myself, and then I did find that once everything was done here I threw myself back into drawing, and I find that very therapeutic for myself, and it's possibly opening up another door, and it's going into tattooing" (Focus Group 3; participant 2)

5.3.3.6. Treatment regime

This outcome domain captures how participants spoke about the impacts of their treatments on their daily lives. Treatment and the associated burdens it places on patients and carers was a topic frequently discussed. Complex treatment regimes, including the wearing of pressure garments for 23 hours a day, massaging and creaming several times a day often took its toll on the participants and some struggled to adhere to the routine 100%. An online participant suggested it could be difficult to adhere to the ***treatment regime*** and implied there is a connection between adherence and the ***appearance of the scar*** (*Scar features),* the location of the scar, and ***psychological well-being***. In the following quote, the participant chose to wear the gloves and shorts as recommended, but was reluctant to wear the facial garment when out in public:

"I was advised to wear these 23 hours a day, and the gloves and shorts I probably wore close to that. However, entering my first year in Uni[versity] was difficult enough, to begin with my healing wounds. I only wore the facial garment in the privacy of my own room + when

I slept. This probably ended up being around 12 hours a day". (Online focus Group 1; participant 3)

Many relied on and greatly appreciated help from family and friends with their treatment but recognised the significant burden this placed on them:

"Yes, it also put a lot of strain on mum because there's an awful lot to do, and with the plasters and bit that is an awful... days were taken up basically just doing all the bits and pieces, having to put cream on three times a day and all that sort of thing, but yes it's a lot to do but you manage, you get by, it sorts itself out". (Interview; participant CA04).

Having to travel frequently to attend ***frequent hospital appointments*** *(Treatment regime)* left participants ***feeling like a burden*** *(Treatment regime)* to relatives and friends. Participants may be required to attend the hospital several times per week:

"Yes, I was back to [main burns hospital] three days a week, Monday, Wednesday, Friday". (Interview; participant EG06)

"I don't need mum to care for me, she's gone back to work. She's only gone back part-time, because obviously I still need quite a lot of hospital appointments and stuff like that". (Interview; participant CA01)

Treatment for a burn injury can have a ***recovery time*** *(Treatment regime)* of up to two years and beyond. At the start of treatment, details and information can be hard to absorb at this early stage especially when also dealing with their ***psychological well-being*** following the burn injury. Understandably, patients were keen for their burns to heal as quickly as possible but some recognised that

their injuries would need time to heal and that perseverance with the treatment regime was key:

> *"The last two and a half years seems to have dragged for me, because I wanted things to happen there and then now, and I must admit it's been long. But it's not long in a way when you look back, you think well actually…"* (Focus Group 1; participant 2)

> *"Time is definitely an important factor in recovery. The tissue takes a long time to heal itself, as much as I would love it to instantly repair. I guess it's a combination of time, patience, and commitment to things like the pressure garments and the massaging, physio etc".* (Online Focus Group 1; participant 2)

For some participants ***recovery*** *(Treatment regime)* was specifically about ***treatments*** *(Treatment regime)*. They described how they were reluctant to try pressure garment therapy because they were uncertain whether it would do any good. One participant explained how she thought the pressure garments would cause her additional ***pain*** *(Scar sensation)* but changed her mind after wearing them for a while:

> *Interviewer:* *"You sounded a bit reluctant to give up on the pressure garment, is that right, having got into it and then..."*
>
> *Participant:* *"At the beginning I think if I'd have been given the choice to say you don't have to wear it, I think if I'm honest I would have thought excellent, no I don't want to wear it, there's no way I want to wear it. But because [Name] was so insistent, and my husband was, "Well you've got to give it a go." Okay, I'll give it a go, and I was really surprised at how it helped with the pain. I don't think I could ever have... although it was getting the right top, and this little piece in here, and the seaming, getting the fit and everything, yes I can't believe how it overcame the pain".*

Interviewer: *"And your reluctance, to begin with, was because you felt it was going to be more painful?"*

Participant: *"Be more painful, absolutely, yes, absolutely, I really thought how can this be less painful than I'm experiencing already? I couldn't understand I don't think how something so tight is going to make it better. But it did, and the scarring is so much... so improved".* (Interview; participant EG02)

5.3.4. How the findings relate to objectives 3 and 4 of the thesis

5.3.4.1. The range of outcomes elicited

Analysis of the data resulted in six outcome domains with 33 associated outcomes. Data to support all of the 33 outcomes were identified in the interview dataset, and data to support 28 (85%) of the outcomes were identified in all three datasets. There was only one outcome, ***guilt*** *(Psychological well-being)*, which occurred in just one of the datasets (interviews). Five further outcomes were identified in two of the datasets: ***Anger***, **loss of identity** *(Psychological well-being)* and ***frequent appointments*** *(Treatment regime)* in the interviews and online focus groups and ***depression*** *(Psychological well-being)* and **driving** *(Returning to a normal life)* in the interviews and face-to-face focus groups. Table 5.5 summarises the outcomes discussed by participants in each dataset.

Table 5.5 Summary of outcomes interpreted in each dataset

	PEGASUS Interviews	OSCAR Face-to-face focus groups	OSCAR Online focus groups
Number of participants:	**n=24**	**n=11**	**n=5**
Scar features			
Colour	√	√	√
Dry, cracked skin	√	√	√
General appearance	√	√	√
Height and thickness	√	√	√
Scar sensation			
Itchiness	√	√	√
Lack of feeling	√	√	√
Pain	√	√	√
Sensitivity	√	√	√
Discomfort	√	√	√
Mobility, movement, and function			
Function	√	√	√
Mobility	√	√	√
Range of movement	√	√	√
Psychological well-being			
Anger	√	x	√
Depression	√	√	x
Fear	√	√	√

	PEGASUS Interviews	OSCAR Face-to-face focus groups	OSCAR Online focus groups
Loss of identity	√	x	√
Guilt	√	x	x
Protection and security	√	√	√
Self-confidence	√	√	√
Stress	√	√	√
Support network	√	√	√
Trauma	√	√	√
Vulnerability	√	√	√
Returning to a normal life			
Getting out and about	√	√	√
Driving	√	√	x
Hobbies and pastimes	√	√	√
Acceptance	√	√	√
Returning to work or education	√	√	√
Treatment regime			
Daily routine	√	√	√
Feeling like a burden	√	√	√
Frequent appointments	√	x	√
Lots to deal with	√	√	√
Recovery time	√	√	√

5.3.4.2. Characteristics of the samples

Recruitment to this study proved to be challenging and there were low numbers of participants in the face-to-face and online focus groups. Ninety percent of participants identified as white with only the interviews including other ethnicities (n=4). Across all of the datasets, there was a spread of age groups participating. Overall, 60% of participants were male. Six (55%) of the face-to-face focus group participants and four (80%) of the online focus group participants were female. A majority of the participants in the interview (n=20, 83%) and face-to-face focus group (n=9, 83%) datasets reported having burns caused by either flame or scald. In the online focus group dataset, two (40%) participants reported burn or scald related injuries. Of the participants reporting the total burn surface area (TBSA), six (25%) participants in the interviews and three (60%) participants in the online focus groups reported having a TBSA of less than 10%. Whereas the largest proportion of participants in the face-to-face focus groups (n=4, 36%) reported a TBSA of between 21% and 30%. Table 5.1 provides a full summary of participant characteristics.

5.3.4.3. The depth of data around the outcomes produced by each data collection method

This section aims to compare and discuss the differences and similarities between the data collected by each method.

Illustrated below, with examples from all three of the datasets, is an interpretation of the extent of the detail (a proxy for depth) provided by participants on the outcomes important to them. See Table 5.6 for a summary of the similarities and differences between the data collection methods.

Table 5.6 Similarities and differences between data collection methods

Item	Description	PEGASUS Interviews n=24	OSCAR Face-to-face focus groups n=11	OSCAR Online focus groups n=5
Differences				
a.	Deeper personal information elicited because the interviewer had more time to probe for additional information	√	x	x
b.	Temporal shifts of outcome priorities were identified	√	x	x
c.	Participants may say what they perceive the interviewer wants to hear	√	x	x
d.	Participants are challenged and are able to question the opinion of others	x	√	x
e.	Participants supported and empathised with other members of the group	x	√	√
f.	There was potentially less time to explore each topic	x	√	√
g.	There was limited time for each participant to speak	x	√	x
h.	Replies were spontaneous	√	√	x

Item	Description	PEGASUS Interviews n=24	OSCAR Face-to-face focus groups n=11	OSCAR Online focus groups n=5
i.	There were some off-topic discussions	x	√	x
j.	Transcripts occasionally made less sense because of interruptions	x	√	x
k.	Online participants potentially had a longer time to reflect on their answers	x	x	√
Similarities				
l.	Stories and context were provided by participants to illustrate their answers	√	√	√
m.	Sensitive and emotional issues were discussed	√	√	√
n.	Participants reported enjoying taking part because they have not previously had an opportunity to talk to others outside of the clinical team, friends and family, about their accident and injuries	√	√	√
o.	Inconsistencies in the narrative were identified	√	√	√

The interviews gave the participants time and opportunity to give detailed information about their injuries and their treatment regimes and how these have affected their working and private lives *(items a, and l, table 5.6).* Additionally, interviews provided the interviewer with the opportunity to probe deeper on how outcomes have affected a participant's life and their hopes for recovery. Consequently, the elicitation of further information is an opportunity less likely to occur in focus groups. In the following quote, the participant described how forward planning and being organised is the key to successfully combining treatment with everyday life. The participant also described how they look forward to the time when they no longer have to incorporate this into their daily life:

Interviewer: *"That's very lovely to hear, and you obviously have been keeping up this routine, and the pressure garments, massage, and creaming, how has that had an impact on you on your life really?"*

Participant: *"The only time it really affects me, because I don't have to work full time it's not impacted that so much. I have to work every other Saturday for a whole day and I don't get to massage it at lunchtime, because I don't want to do it at work, I don't want people seeing it, I'd feel uncomfortable about that. But all the rest of the time I'll do an extra one as soon as I get home from work and then do one late at night then. But I have to always plan ahead, and when we're on holiday or if I'm away on business, which I do once a year, it's really tricky. I've just been away, lucky me, I've just done a [Country] safari, and we were getting up to go on game drives at five o'clock in the morning, so I was having to get up at four o'clock in the morning so I could schedule in quarter of an hour to do my massaging. So it's just things like that, I'm not going to say it's a pain because it's part of everyday life, and you just have to accept it, make the best of it and just go no, if I want to give it the best chance of being a good scar that's not so noticeable then I've got to do this. But by golly am I looking forward to that three-quarters of an hour I'm going to have free*

> *when it's done. I'm going to celebrate that 45 minutes every day".* (Interview; EG08)

All data collection methods produced data about the emotional effects of a burn injury *(item m, table 5.6)* although based on my interpretation the most emotional arose in online focus group 1:

> *"Yesterday it was really hot and a man came up to me saying that it was hot but that it must be worse for me in a plastic mask. This really wound me up because it's like well duh, obviously it's horrible but it's of no relevance to you. I've found that wearing this has made me really angry practically all the time. When I first started wearing it I could deal with it but now, after just over a year, I can't take the constant staring, pointing, whispering, laughing and nasty comments".*(Online Focus Group 1; participant 1)

It is difficult to know whether the open disclosure by the participants in online focus group 1 was because the participants had similar burn injuries, or whether it was down to the nature of an online focus group i.e. anonymity, or maybe the personality of the individuals concerned *(item m, table 5.6)*. In the quotes below, the online participants indicated how they have never had the opportunity to speak to other people who have experienced a similar situation:

> *"I agree with [participant X], it has been so nice talking to people who know what it's like and have experienced the good and bad alongside you. I haven't come across anyone who fully understands what it's like so when I'm having a bad day I often feel completely alone because it seems like such a unique situation".* (Online Focus Group 1; participant 1)

This was not unique to the online focus groups; participants expressed the same feelings at the end of the face-to-face focus groups. Unfortunately, these comments happened after the recordings had finished, but participants explained to the facilitators how much they had appreciated the opportunity to meet and talk to others who have suffered a burn injury *(item n, table 5.3)*. The interactive nature of focus groups may have helped to foster the mutual support and disclosure witnessed. The researcher (Janet Jones) did not conduct the PEGASUS interviews so it is also possible that this type of information were discussed after the interview recordings had finished.

In contrast to the experiences of the participants in the interviews, face-to-face focus groups and online focus group 1, the participants in online focus group 2 claimed not to have received any negative comments from members of the public. This may be because the participants wanted to appear strong and psychologically unaffected by the burn injury or maybe because no one had been negative during the discussion. Conversely, interpretation of the quote below may be that the participant did receive negative comments and the way they dealt with them was to take the opportunity to tell others how dangerous chemicals can be if handled incorrectly. Similarly, some of the participants in the interviews, face-to-face focus groups and online focus group 1 described how they would inform others about the dangers associated with burn injuries:

> *"I have not received any negative comments about my scars or pressure garments. Generally, they have led to question how I did it. I take this as an opportunity to warn others against using chemicals that are being sold widely that can be very harmful".*

(Online Focus Group 2; participant 1)

Focus groups function on the relationship and interaction between participants *(Item d, table 5.6).* For example, focus group participants are able to disagree with or question the views of another participant. In the quote below, the interaction between two participants revealed their views on treatment and healing:

P3	*"If I lean over a certain way like that with my wrist, my wrists are absolutely burning with it, and I found them pressure garments make my skin itch terrible on mine if you've got them on".*
Facilitator	*"Oh you find them itchy?"*
P3	*"Hmmm hmm".*
P1	*"But I think that's just the healing process, they do that anyway, because the one on my leg is only about that long, and the full thickness it does itch, and when I scratch it my little toe moves because it's by where the nerve endings are for my toes. So that's just the healing process in general".*
P3	*"I try my best not to scratch it because you can make the scarring worse".* (Focus Group 2; participants 1 and 3)

Discussion among the participants in face-to-face focus group 3 revealed how one of them had received different treatment compared to the others despite the fact that they all attended the same burns unit. This type of information was not present in the other face-to-face focus groups, the online focus groups or the interviews. Due to the interactive nature of a focus group, it was always possible that this type of information may be uncovered:

P1: "You see, so there was no way that you could get… oh no, I had nothing… as I said I had three measurements".

P3: "They still check every three months to see if my measurements have changed".

P1: "No I didn't have anything like that".

Facilitator: "Sounds like some very different experiences of pressure garments".

P4: "That's interesting isn't it?"

(Focus Group 3; participants 1, 3 and 4)

There were often informative, supportive exchanges between focus group participants *(item e table 5.6).* The following quote shows how one participant, further along with their recovery than a fellow participant, explained how long the process might be:

P1: "She said [OT] it's because I'm right handed, you use the right more, and the left is taking longer to do, to be honest".

P3: "It takes a good while".

P1: "It does take a long time".

P3: "These are still tight now, and that's two and a half years ago".

P1: "I've got a bit to go then".

P3: "Yeah, because it's you never think they're going to come…".
(Focus Group 1; participants 1 and 3)

The face-to-face and online focus group participants tended to be supportive of each other, empathising when participants recounted traumatic times. However, this type of interaction is not possible in one-to-one interviews. This type of data

not only provides insights into a participant's individual feelings and experiences but also sheds light on whether others share these feelings or whether they are unique to that individual. These conversations tended to centre on appearance and feeling vulnerable to the looks and stares of other people:

> *P2: "Yeah, on the train today, because it was so hot on the train, and because on my arm… it was packed on the train as well so it made it even worse, and there was this girl sat in front of me and I was watching her and she was having a proper good gawp at it, and then she finally looked up at me and I was like… and then she looked away really awkwardly and I'm like…"*
>
> *P4: "They put their own self into that situation because you don't want to be… here we go again the victim, but you're not the victim are you, it's just something that's happened".* (Focus Group 2; participants 2 and 4)

> *"[Participant X], I'm so sorry you have to go through all this, it can really be horrible and people are so ignorant about it and annoying. I hope it doesn't bring down your confidence and that hopefully you will be able to be rid of the mask soon!! I remember almost crying when I was told at a check in appointment that I no longer needed to wear my garments".* (Online Focus Group 1; participant 3)

For many participants, their priorities for recovery changed as time progressed *(item b table 5.6).* A temporal shift in outcome priorities was more evident, although not exclusively so, in the interviews compared to the face-to-face and online focus groups. This temporal shift may be more noticeable in the interviews because compared to focus groups interviews can naturally facilitate the elicitation of this type of data. Most participants relate their stories with a chronological focus. A shift in priorities may occur when the initial priority for recovery improves, thereby shifting a participant's focus. For instance, the

participant in the quote below could only initially think about why this happened to them. However, a focus on appearance subsequently replaced the initial mental trauma:

Interviewer: *"How did you feel about that time?"*

Participant: *"I was horrified, miserable, horribly depressed and just thinking God get me out of here".*

Interviewer: *"Get you out of hospital treatment you mean?"*

Participant: *"Yes, just I'm fed up of being poorly, and not feeling great, and I just want to be back to normal, and how can one stupid trip result in all of this palaver, and where is it going to end?"*

Interviewer: *"You said when you were at work you didn't want people to see it, was that seeing the pressure garments or was that seeing the scar or both?"*

Participant: *"Oh no, they see the pressure garment, I'm quite happy in t-shirts and stuff, but I'm not comfy with people apart from my nearest and dearest seeing the scar it's big and I think it's quite shocking".*

Interviewer: *"Is that still now you still feel it looks…"*

Participant: *"Yes".*

Interviewer: *"You've said several times that it's very slowly getting better but you still feel it's shocking or could be shocking for others to see?"*

Participant: *"Yes, well it's just different isn't it? And anything that's different people go oh what have you done? I'm fed up with telling people about it, I don't want to tell people anymore".* (Interview; participant EG08)

Whilst it may be understandable how and why a participant's priorities may change over time there is an inconsistent narrative running through some of the interviews and face-to-face and online focus groups *(item o, table 5.6).* For example, one participant explained at the beginning of the interview how getting

their mobility and movement back was the most important factor for their recovery:

> *Participant:* *"They gave me exercises what I done at home, they put my arm right up and stretching and that, and got things going again.*
>
> *Facilitator:* *Is that back to normal?*
>
> *Participant:* *It is yes, it's great, yes, that's one thing I did want. I could put up with the skin, the look of it"* (Interview; participant CA04)

However, through the rest of the interview references to appearance occurred frequently whereas reference to mobility and function did not. This was particularly noticeable when the facilitator asked what they think researchers should assess in a trial on pressure garments:

> *"I used to look in the mirror and I used to stand and cry because I used to think I don't want this, I don't want to look like this"* (Interview; participant CA04)

In the following example, the participant implied that function was the most important aspect of their recovery only to change this to pain and appearance later on. The conversation proceeded as follows:

> *Interviewer:* *"What would you say has been most important for you given the treatment you've had, what's been most important for your recovery?"*
>
> *Participant:* *"I think the pressure garment was very because that just helped me get on with life normally as such really, well as normal as I could anyway, whereas I would have probably ended up with a bandage or something round it all the time if they wasn't around sort of thing. So I would have had one of them on constantly really, but it wasn't obstructive at all, because it was on the hand and it was quite tight I could get on with my normal routine of*

driving and messing around with the cars and that sort of stuff".

Later on the conversation:

Interviewer: "I may be repeating myself, I do apologise, what was the most important thing that you wanted to achieve through the treatment you were getting?"

Participant: "Just to get rid of the pain and make that look as best as possibly really, so that was it really".

Interviewer: "So you wanted to look good, and get rid of this pain?"

Participant: "Yes, get rid of the pain and the uncomfortableness, yes". (Interview; participant EG07)

Between these two conversations, the interviewer asked the participant how they felt about looking at the scar and went on to explain how some people can feel uncomfortable looking at their scar. It is therefore possible that the interviewee felt they should be recognising appearance as a key feature in their recovery *(item c, table 5.6)*.

As is the nature of face-to-face focus groups, there was limited time for the facilitator to explore some topics in detail *(items f, and g, table 5.6).* In fact, each of the face-to-face focus groups could have lasted much longer and indeed conversations between participants often continued after the conclusion of the groups. In comparison to the interviews and online focus groups, participants in face-to-face focus group 2, strayed off-topic for several minutes to talk about the location of the group *(item i, table 5.6).* Also in the same group participants talked over each other *(item, j table 5.6)* on a couple of occasions.

Although the interviews and face-to-face focus groups produced detailed replies, participants in the face-to-face focus groups were more spontaneous in their replies compared to those in the online focus groups *(item h, table 5.6)*. Online asynchronous participants have the opportunity to take time to consider their answers but it is impossible to know if the participants took advantage of this. Compared to interview and face-to-face focus group participants however, the online focus group participants were able to edit their replies before posting them to the forum *(item k, table 5.6).* For example:

> *"It's been a really tough year and a bit so far. The accident I had happened two weeks before my final exams at Uni[versity] were due to begin so consequently I could not sit them. I was not ready to sit them over summer so I decided to go back to Uni. Obviously, this was daunting because I did not know anyone as all of my friends had graduated. It was worsened by the fact that I had very little hair (my hair was shaved off completely because the surgeon's took skin from my scalp for the graft) and was wearing the plastic mask. I knew that the other students would want to ask me about it but also probably wouldn't so I thought the best thing to do was to stand up in front of everyone in my year and just tell them what happened. This worked because it meant that everyone knew and we could just move on. I have finished Uni now though, graduate on 6th July!"* (Online Focus Group 1 Participant 1)

Participants in the online groups were encouraged to use emojis and/or abbreviations. The theory behind this is that emojis may be able to fill the void when there are no verbal cues to pick-up on, and they are a language familiar to most people who use online technology. Interestingly, none of the online focus group participants chose to do so. It is difficult to know why this was. It may be that participants considered the subject too serious to use emojis and

abbreviations. Alternatively, it may be because the facilitator did not use any emojis or abbreviations and the participants followed suit.

The differences between the datasets do not appear to have directly influenced the range of outcomes identified. Compared to the face-to-face and online focus groups the interviews produced more in-depth data around the outcomes, this may be because the interviewer had more time to probe for information. Nevertheless, meaning and understanding about why outcomes are important to patients are present in the focus group datasets. Appendix 25 is a table of additional supporting quotes relevant to this chapter.

5.3.4.4 Comparison of the OSCAR findings and the original PEGASUS interview findings

The PEGASUS paper identifies that many outcomes are interlinked, and they report that participants talked about some of the unexpected benefits of pressure garments, such as the protection and security they provide. These are comparable to the findings of my re-analysis of the interviews and to the findings of the face-to-face and online focus group data. Table 5.7 shows a comparison between the outcome domains identified in this research study to those of the PEGASUS study.

Table 5.7 Comparison between the outcome domains of the OSCAR study and the PEGASUS study

OSCAR study domains	Domains identified through the original analysis of PEGASUS data
Scar features	Scar characteristics
Scar sensation	Scar sensation
Mobility, movement, and function	Movement and function
Psychological well-being	Psychological distress, adjustments and a sense of normality
Returning to a normal life	
Treatment regime	Treatment burden
	Body image and confidence
	Engagement in activities
	Impact on relationships

PEGASUS data coded as “adjustments”, “sense of normality”, and “engagement in activities” are coded against the OSCAR study outcomes “**getting out and about”, Hobbies and pastimes” “returning to work or education”** and **“acceptance”** within in the domain **“returning to a normal life”**. The PEGASUS domain “movement and function” is similar to the OSCAR study domain “**Mobility, movement and function”** although the OSCAR coding breaks the data into three outcomes separating out **mobility.** “Body image and confidence” in the PEGASUS dataset are included in the OSCAR study outcomes **“self-confidence”** and **“vulnerability”** within the **“psychological**

well-being" domain. "Impact on relationships" is not present in the OSCAR study domains and outcomes. The differences between the OSCAR study and PEGASUS study findings are discussed further in Chapter 6, section 6.3.3.

4.3.4.5.Resources required for each data collection method

To date, reports of qualitative research findings related to COS development do not include details of the time and resources required to carry out qualitative data collection. Researchers often reported how long recruitment took and/or the incentives paid to participants but information on the full impact of conducting this type of research in terms of time and money was lacking. Provided in Table 5.8 are the costs of generic items which, once obtained, can be used for future research studies. Table 5.9 provides details of the static costs related to this research study. These costs would remain the same regardless of the number of interviews, face-to-face focus groups or online focus groups and Table 5.10 summarises the variable costs required for each data collection method in this study. If conducting a greater or a smaller number of interviews, face-to-face focus groups or online focus groups these costs would vary accordingly.

Table 5.8 Costs of generic items (items that can be used for future research studies)

Item	Estimated Cost (£ sterling)
Personal computer	£750.00
Analysis software (i.e. NVivo)	£900.00
Digital recorder with encryption	£346.00

Table 5.9 Static costs (regardless of the number of interviews or focus groups)

Type of Cost	Reason	Estimated costs (£GBP)		
		PEGASUS study number of interviews (n=24)	OSCAR study number of face-to-face focus groups (n=3)	OSCAR study Number of Online focus groups (n=2)
OT time	Identification of participants	£183.00	£244.00	N/A
Researcher time	Identification of participants	N/A	N/A	£182.00
Researcher time	Preparation of study materials	£675.00	£675.00	£338.00
Researcher time	Attending the ethics committee	£68.00	£68.00	N/A
Online set-up	Website set-up and	N/A	N/A	£174.00

Type of Cost	Reason	Estimated costs (£GBP)		
		PEGASUS study number of interviews (n=24)	OSCAR study number of face-to-face focus groups (n=3)	OSCAR study Number of Online focus groups (n=2)
	maintenance			
Online set-up	Online survey development	N/A	N/A	£150.00
Total cost		**£926.00**	**£987.00**	**£844.00**
Cost per focus group, per online focus group and per interview		**£38.58**	**£329.00**	**£422.00**

Table 5.10 Variable costs (will differ according to the number of interviews or focus groups)

Type of Cost	Reason	Estimated costs (£ GBP)		
		PEGASUS study number of interviews (n=24))	OSCAR study number of face-to-face focus groups (n=5)	OSCAR study number of online focus groups (n=2)
Researcher time	Making calls and/or sending emails to discuss the study and to make arrangements	£59.00	£56.00	£34.00
Researcher time	Sending out study information	£34.00	£17.00	£8.00
Researcher time	Sending confirmation details	£34.00	£21.00	£8.00
Researcher time	Reminder calls/emails	£34.00	£20.00	£6.00
Researcher time	Travel time to focus group/interviews	£405.00 (1 interviewer)	£202.00 (1 focus group only, 2 facilitators)	N/A

Type of Cost	Reason	Estimated costs (£ GBP)		
		PEGASUS study number of interviews (n=24))	OSCAR study number of face-to-face focus groups (n=5)	OSCAR study number of online focus groups (n=2)
Researcher time	Preparing and running the focus groups/interviews	£608.00 (1 ½ hours per interview)	£270.00 (2 facilitators)	£85.00 (a ½ hour per day for 10 days x 2)
Researcher time	Data analysis	£4457.00	£507.00	£338.00
Postage	Sending out study information	£24.00	£25.00	N/A
Telephone calls	Talking to participants about the study	£4.00	£9.00	£1.00
Expenses	Researcher travel expenses	£240.00	£108.00	N/A
Expenses	Participant travel expenses	N/A	N/A	N/A
Expenses	Refreshments	N/A	£43.00	N/A
Expenses	Thank you gift voucher/incentive	N/A	N/A	N/A
Expenses	Transcription	£1130.00	£362.00	£0.00
Total cost		**£7029.00**	**£1640.00**	**£480.00**

Type of Cost	Reason	Estimated costs (£ GBP)		
		PEGASUS study number of interviews (n=24))	OSCAR study number of face-to-face focus groups (n=5)	OSCAR study number of online focus groups (n=2)
Cost per focus group, per online focus group and per interview		**£292.88**	**£547.66**	**£240.00**
Costs for the OSCAR study proposed scenario of 5 face-to-face focus groups, 5 online focus groups, and 24 interviews		**£7029.00**	**£2738.30**	**£1200.00**

Basis of calculations

Table 5.11 outlines the unit costs, which formed the basis of the calculations above, and Table 5.12 details the calculation of researcher time.

Table 5.11 Summary of unit costs

Item	Unit cost
Salary – Occupational therapist based on mid-scale of NHS band 6	£31,698 per annum, £16.25 per hour (see calculation of hourly wage below)

Item	Unit cost
Salary – researcher based on lower spine point, University of Birmingham grade 7.(Equivalent to a novice researchers salary)	£31,604 per annum, £16.88 per hour (see calculation of hourly wage below)
Postage first class – per large letter	£1.00
Travel expenses	£0.40 per mile
Transcription of face-to-face focus groups	£1.10 per transcribed minute
Transcription of interviews	£0.95 per transcribed minute
Telephone calls (BT consumer guide dated September 2017	£0.12 per minute

Calculation of hourly wage

Researcher

Academic staff do not officially have allocated hours but in general, university staff work a 36-hour week that is roughly 7.2 hours per day.

7.2 hours per day x 5 days x 52 weeks = 1872 hours.

Annual salary £31,604 / 1872 = £16.88 per hour.

Occupational Therapist

NHS staff generally work a 37.5-hour week that is roughly 7.5 hours per day.

7.5 hours per day x 5 days x 52 weeks = 1950 hours.

Annual salary £31,696 / 1950 = £16.25 per hour.

Table 5.12 Calculations of researcher time

Calculations of researcher time
Preparation of study materials for face-to-face focus groups and interviews based on 2 hours per day over 4 weeks (40 hours) and 2 hours per day over 2 weeks for the online focus groups (no ethics, HRA or R&D documentation required).
Attendance at ethics meeting, two researchers for two hours.
Calculations for the data analysis of the interviews are based on 11 hours per interview (264 hours), 10 hours per face-to-face focus group (30 hours) and 10 hours per online focus groups (20 hours).

Generic costs

IT services at the University of Birmingham advised on the cost of a personal computer.

The NVivo cost was obtained from the QSR NVivo website on 13th July 2018.

The cost of a recorder is an average cost (as of 13th July 2018) of digital recorders with encryption: Olympus DS-3500 £262.79, Olympus DS-7000 £394.00 and Philips DPM 8000 £381.59.

Regulatory approvals

The time required to obtain regulatory approvals can vary greatly depending on the purpose and design of a research study. For example, this study involved recruiting NHS patients and therefore the following approvals were required (aggregated length of time taken to receive them): institute sponsorship (1 month), ethical and Health Research Agency (HRA) approval (3½ months) and, research and development (R&D) approvals (4 months).

5.4. Summary of findings

This chapter has reported the findings from the re-analysis of the PEGASUS study interviews and the OSCAR study face-to-face focus groups and online focus groups. It has discussed the similarities and differences between the datasets in relation to objectives 3 and 4 of the thesis (Chapter 1 section 1.6.2). Across the three datasets, thirty-three outcomes important to participants were identified, and these were grouped into six outcome domains. Illustrative quotes were used to describe the findings in each of these domains.

Each of the data collection methods produced a very similar range of outcomes. There was a diversity of participant characteristics providing a spread of age and gender across the datasets, but due to the low numbers in the focus groups (in

particular the online focus groups), it was not possible to achieve a maximum variation sample. Flame and scald were the most common cause of injury but participants who had suffered other types of burn injury were included in all datasets. All of the methods generated information on how burn injuries and their associated treatments affect participants' lives. Overall, the interviews generated data to support all of the elicited outcomes and produced the greatest amount of in-depth data. This may be because the interviewer had time to probe further by following up participants' comments whereas this opportunity did not always arise in the face-to-face focus groups as conversations moved on quickly. Opportunities to delve deeper did arise in the online focus groups and some participants in online focus group 1 did expand on their answers. However, it is difficult to assess how effective an online focus group is at achieving this with such a low number of participants. In the main, but not exclusively, the interviews highlighted temporal changes in participants' priorities. Inconsistencies in narratives were uncovered in some of the interviews and face-to-face focus groups. These inconsistencies can arise during an interview or focus group if the participant feels that they have to say what they think the facilitator wants to hear, but at other points during the discussion, the participant may express their true opinions. Another explanation for inconsistencies in the narrative may be that the participant is unclear about what is important to them and changes their mind as the discussion continues. It is therefore important that researchers are aware of the possibility that this type of inconsistency may arise and should consider the reasons for any inconsistencies during data analysis.

A brief overview of the resources associated with setting up and running a research project using each of the three data collection methods was provided. In this study, due to recruitment difficulties data saturation might not have been reached for the face-to-face and online focus groups. In all likelihood, saturation would have been reached with five face-to-face focus groups and five online focus groups. In this instance, online focus groups would be the most cost-effective (Table 5.10).

Chapter 6 provides a detailed discussion of this research, how it adds to the existing knowledge on qualitative research in COS development and its strengths and limitations. Finally, recommendations for future research are made and guidance is provided on key reporting standards for those using qualitative research approaches as part of a COS development.

CHAPTER 6: DISCUSSION, CONCLUSIONS, KEY REPORTING STANDARDS AND FUTURE RECOMMENDATIONS

6.1. Introduction

This chapter presents a summary of this research. It relates the findings to the current literature, discusses the implications of the study and provides recommendations for future research. As far as I am aware, this research is the first to directly compare data collected using different qualitative data collection methods to elicit outcome data from patients with a view to providing guidance to inform COS development. The research has included novel methods of primary data collection such as online asynchronous focus groups and the Traditional Pearl Growing methodology to identify comparative data on face-to-face and online focus groups.

The aims of this thesis were to: 1) build knowledge of how qualitative research with patients can effectively inform the development of COS that resonate with the range of users of trial-derived evidence; 2) compare the use and utility of three qualitative data collection methods for understanding which outcomes are most important to patients and why.

There is currently little guidance on using qualitative research methods to understand outcomes important to patients for COS development (16, 53, 65, 66). Likewise, when reporting on the resources required to conduct qualitative research papers only tend to report on the length of the focus groups or interviews (115). This research has provided further insights to build upon existing knowledge.

6.2. Summary of key findings

6.2.1. Objective 1

To review critically the methods used to develop core outcome sets with a particular emphasis on the participation of patients and carers and qualitative methods.

My 2017 review of the literature reporting the development of a COS (82) (see Chapter 2) found that 29% of COS development exercises using qualitative research methods included patients and carers. An evaluation of COS development studies in progress revealed an increase in patient participation. The review (82) found that patients and carers participate in methods to identify outcomes and methods to prioritise outcomes. Not all papers reported the numbers involved but of those that did the majority of patients and carers were participants in the identification of outcomes (interviews, focus groups, surveys). Of the papers reporting the use of qualitative methods four, reported using interviews as the only qualitative data collection method (62, 209-211), four used focus groups only (61, 86, 183, 212), and two combined interviews with focus groups (87, 213). None of these papers reported an underlying methodology for their qualitative research. When patients and carers were involved in the prioritisation of outcomes (Delphi, nominal group technique, consensus meetings) they were in the minority with most participants being HCPs or academics. Overall, the reporting of the use of qualitative methods was variable

between the papers. The review concluded that to aide future COS development further research was required in order to ascertain the role of qualitative methods with patients, to assess the depth of the data produced from different qualitative approaches and the practicalities of undertaking qualitative research as part of COS development. Furthermore, the review recommended key reporting standards for qualitative research in COS development.

6.2.2. Objective 2

To review critically the existing research that has compared the use and utility of novel online qualitative data collection methods (focus groups) available to COS developers, with more traditional face-to-face approaches.

My review of the literature comparing face-to-face and online focus groups (Chapter 3) concluded that face-to-face focus groups are the best method to generate in-depth data and participant interaction. Nevertheless, when deciding on which qualitative data collection method to choose researchers will need to consider issues such as the context of the research, the study question, and the intended population.

6.2.3. Objectives 3 and 4

To compare the outcomes that are important to patients elicited through three different qualitative data collection methods (interview, face-to-face focus

groups, online focus groups), and to identify any differences and similarities between the methods. Specifically, the range of outcomes elicited the depth of the data around the outcomes and the characteristics and diversity of the sample.

To document and report the related resource use (i.e. time and cost) and the strengths and limitations associated with each approach.

The primary research collected data from adult burns patients using face-to-face and online focus groups. These data were compared with interview data previously collected as part of the PEGASUS study. Thirty-three outcomes were interpreted from the data and these were organised into six overarching outcome domains; Scar features; Scar sensation; Mobility, movement and function; Psychological well-being; Returning to a normal life; and Treatment regime. All of the data collection methods in this research study generated broadly similar outcomes, regardless of the fact that there were only a small number of face-to-face and online focus groups.

The required financial resources for this research study were documented and are summarised in three categories; Generic costs (costs of items which can be used for future research studies), static costs (costs which will remain the same regardless of the number of data collection points), and variable costs (costs which will vary depending on the number of data collection points). These figures show that per individual data collection point online focus groups were the cheapest to run with face-to-face focus groups being the most expensive. But if

the costs were scaled up to the OSCAR study's preferred scenario of five face-to-face focus groups, five online focus groups and 24 interviews it is the interviews that become the most expensive to run.

Based on the findings of this research, interviews provide the most in-depth data around outcomes important to patients and are the recommended qualitative data collection approach if researchers have the sufficient time and resources. If COS developers have limited time and resource then online focus groups may be a useful tool to identify outcomes from the patients' perspective.

6.3. Summary of findings in the context of existing knowledge

6.3.1. Patient participation in core outcome set development

A review of papers reporting the development of a COS, undertaken by Gargon in 2014, aimed to identify papers assessing which outcomes are to be measured in clinical trials in a specific health condition, and to describe the methodological techniques used (16). At this time, Gargon found that just 16% of the included studies reported the involvement of public representatives in COS development (16). Public representatives in Gargon's papers included patients, carers, patient-support group representatives and service users. The review also found that it was sometimes difficult to identify the key features of the COS development pathway and called for improved reporting of COS development

(16). Additionally, the lack of methodological guidance for those undertaking a COS development exercise was highlighted. An update of Gargon's review published by Gorst in 2016 reported an increase in patient and public (again this includes patients, carers, patient-support group representatives and service users) participation and/or involvement and a more structured approach to the reporting of the key features of a COS development (81). However, there was not an improvement in the reporting of qualitative methods. My 2017 review of the participation of patients and carers and the use of qualitative research methods in COS development found that the use of and the reporting of these methods was still poor (82). A recent review, published in 2018, of the COMET database has revealed that of the 15 newly identified COS studies, eight reported they had included patient and public representatives (214). Only seven however, reported details on public participation and none of these used qualitative methods. One explanation of this may be the lack of clear guidelines on how to include patients and/or carers in COS development and the lack of evidence about the benefits of using qualitative methods. The OMERACT group were one of the earliest to involve patients in the development of a COS and to highlight that outcomes important to patients may differ to those identified by clinicians, thereby reinforcing the importance of including the patient perspective when developing a COS (85). The paper stresses the need to listen and understand the patient before assuming which outcomes are important to them and why, but it does not mention using qualitative research to elicit this information. The authors suggested using qualitative research to help clarify terminology and definitions for use in assessment instruments. The COMET

initiative published a handbook in 2017 (53). This handbook provides guidance to all COS developers on the development, implementation, evaluation of COS and the updating of existing COS. It suggests that qualitative methods may be useful to elicit views on important outcomes that may not be included in a systematic review. It also recommends using patients' words and descriptions, elicited through qualitative data collection, to describe outcomes in the prioritisation stages of a COS development to help to facilitate the participation of patients in these processes. The handbook advocates the transparent write up of the use of qualitative methods including defining the COS development process and detailing how the work has informed the scope of the COS. Nevertheless, the handbook acknowledges that more work is required to enhance the evidence base on the use of qualitative research in COS development.

As acknowledged in the COS literature and found in this research it can be difficult for participants to understand the concept of outcomes (53, 65, 66, 82, 87, 156). Several papers report patients struggling with the idea of outcomes (62, 66, 87) and Keeley (co-authored paper) described participants finding the concept of outcomes obscure and challenging (66) (Appendix 26). Mathers in their conference paper discussed the benefits of asking experiential questions from which outcomes can be interpreted as opposed to direct questions about outcomes (156). Other COS developers incorporating qualitative work with patients agree with this approach, opting to ask questions such as "what should an intervention achieve" (66) or "what makes you feel well" (62) for example. For the OSCAR study, I designed the topic guides and visual guide with the aim of

encouraging experiential narrative from the participants (See Appendices 19, 20 and 21). For example, “What should be assessed in research on pressure garments?” participants found it difficult to think beyond the details of the design of pressure garments rather than what they would like them to achieve in relation to their burn injury. However, when the question was qualified, participants in face-to-face focus group 1 and online focus group 1 did express their opinions on outcomes that they reported as important to them:

Facilitator	*So what about thinking about things that you would like the pressure garments to achieve, rather than the actual pressure garment itself, what kind of things do you think you want them to achieve that you think we should be looking at in research?*
P1	*So they do achieve what you want, they achieve… you’re looking for a better appearance, and they definitely do that, there’s 100% on that.*
P1	*Better appearance is a big factor isn’t it?*
P2	*Yeah, definitely, and the bumpiness*.

(Focus Group 1; participants 1 and 2)

In the focus groups, the question “Tell me about your experiences of pressure garments” generated the most outcomes and data on why the outcomes were important.

For a COS to include outcomes that are important to patients and to make sure that treatments benefit patients it is important to understand the best way of eliciting this information (65). To address this issue, Young (65) held workshops specifically designed to explore the methods and strategies for seeking the input

of patients when developing a COS. One of the findings from these was that patient participation in COS development should be supplemented by patients working as research partners in the design of COS studies. Some of the participants, thinking about participation in COS development, suggested they would prefer to take part in qualitative data collection methods rather than a Delphi. They perceived taking part in an interview or focus group was a more meaningful contribution. Young's paper calls for more methodological research to assess the best ways of seeking patient input into the development of a COS (65). The findings from these workshops resulted in the COMET initiative setting up the People and Public Participation, Involvement, and Engagement (PoPPIE) working group. The group has an international membership and aims to ensure patients have a say in COS development and that the resulting final outcome set is relevant to them (65, 215). The PoPPIE workgroup can advise COS developers on the best ways to include patients in their COS development process.

6.3.2. Reflections on the use of qualitative data collection methods in core outcome set development

This work has provided insight into three different qualitative data collection methods and reported on the similarities and differences between them in the context of range of outcomes elicited, depth of data, characteristics of the sample and the required resources. The following section reflects on the use of these methods and places them in the context of the wider relevant literature.

6.3.2.1. Qualitative methodological approach

The use of and reporting of an underpinning qualitative methodological approach can help the reader to understand how the research aims and questions were explored (216). To date, studies reporting on the use of qualitative data collection methods with patients as part of a COS exercise have not identified an underlying qualitative methodological approach (217).

The process of developing a COS is similar in some ways to the process of developing PROs. For example, concept elicitation in PRO development often uses qualitative research methods with patients to identify and map out relevant concepts (195, 218, 219). Similarly, in COS development qualitative research methods identify outcomes that are important to patients. There is currently no regulatory guidance which explicitly recommends the use of an underlying methodology for qualitative work in the development of a PRO (194). Some of the literature reporting on using qualitative research methods in concept elicitation for PRO development have reported using specific methodological approaches (193, 195, 220, 221). Brédart (220), Cheng (221) and Lasch (195) all advocated the use of an overarching phenomenological approach with data collection and analysis guided by grounded theory. Alternatively, Brod (193) recommended using an overarching grounded theory approach to guide data

collection and analysis. None of the papers provided adequate justifications for using either of these approaches.

Regarding COS, and as discussed in my published paper (82) (Chapter 2) a methodological approach for qualitative research undertaken as part of a COS development needs careful consideration. For example, if the aim is to understand the lived experience of a disease and treatment then a phenomenological approach may be a good choice. COS development is a process consisting of several stages. In the initial stages identification of possible outcomes often happens through systematic reviews, qualitative research methods can be used to complement these lists before they are taken forward to a COS prioritisation exercise. An interpretive description approach is recommended as an appropriate methodology for qualitative research aimed at obtaining a pragmatic list of outcomes through descriptive accounts provided by patients (Chapter 4, section 4.3.1). (169, 172, 180-182).

6.3.2.2. Recruitment

Potentially eligible participants for the face-to-face groups and the interviews were identified from hospital lists. Occupational Therapists made the first contact. There is currently very little guidance on the best ways to recruit participants to online focus groups and studies have used a variety of methods; such as, advertising a study on a website of an appropriate support group (119,

122, 128, 145) (one of the approaches I took for this research); the recruitment of participants from an existing source i.e. from an earlier stage of the study (127); recruiting patients from hospital treatment lists (111); or from those who were unable to attend a face-to-face focus group (98). (An approach I used when my original strategies were unsuccessful. Chapter 4: Methodology and Methods section 4.4.2.2.).

Treweek (185) carried out a study to identify methods to improve recruitment of participants to studies. Although this paper specifically refers to recruitment to RCTs, some of the recommendations are applicable to qualitative research. They recommend the use of telephone reminders, and financial incentives. For this study, offering a financial incentive was not an option as the funds were not available to cover this. However, refreshments were provided at all face-to-face focus groups and, as recommended by Treweek, participants to both the face-to-face and online focus groups received telephone and/or email reminders.

6.3.2.3. Data collection methods

In line with the aims of this research, I chose to collect data using face-to-face focus groups and online asynchronous focus groups with the purpose of comparing the data to those collected through interviews. Interviews can produce rich detailed information on an individual's experiences relevant to the research topic and there is the opportunity for the researcher to build a rapport

with the interviewee (88). The advantages of interviews include the collection of detail rich data, they can be flexible, they can reach vulnerable groups of people and the interviewer can control the discussion (88, 89). Interviews can be time consuming for both the participant and the researcher, and participants may not feel empowered because they are uncertain about what to expect or what is expected of them (88, 89, 222). The qualitative researchers working on the PEGASUS study chose interviews as the best qualitative data collection method to explore, in-depth patients' experiences, patients views of burn injury, their views on pressure garment treatment and to elicit outcomes that are important to patients (105). The topics explored in these interviews made the collected data relevant to my research and therefore the interview data were re-analysed for comparison with the primary collected focus group data.

6.3.2.4. How the design of the study may influence the data collected

The way in which a focus group or interview is facilitated is important in ensuring that relevant data are collected. The quality of the data produced in focus groups depends not only on the skill of the facilitator but also the interaction between the participants (88, 89, 94, 95). It has been suggested that when facilitating online focus groups a more structured approach may be needed compared to that of a face-to-face group (159, 160).

Using different data collection methods to recruit participants to the face-to-face and the online focus groups may have resulted in differing participant characteristics (the online participants were slightly younger and 80% were female compared to the characteristics of the face-to-face focus group participants), which in turn may have influenced the types of data elicited. However, this approach is in line with other literature comparing different qualitative data collection methods (140, 145, 152). Similar to Guise (145) I found that the outcomes (themes) interpreted from the data of each dataset were similar.

My lack of experience as a focus group facilitator may have affected the data produced. By attending focus group training, discussing the structure and aims of the focus groups with my supervisors and including them as co-facilitators, I hoped to compensate for my lack of experience. Overall, I feel that the focus groups were successful. The data produced in both the face-to-face focus groups and the online focus groups answered my research questions and provided depth of data.

When researching health-related topics, focus groups facilitated by someone who is not a clinician may help participants to feel free to discuss the topic openly and honestly. If a clinician is present participants may feel that they should say what they think the clinician wants to hear rather than what they truly feel (121). For this research, each focus group started with an explanation of our

job roles making it clear that neither the facilitator nor the co-facilitator had any medical knowledge of burn injuries. I believe this declaration led to participants talking freely about how they felt about their burn injury, treatment, and recovery.

6.3.2.5. The depth of data produced per method

Analysis showed that all of the data collection methods interviews, face-to-face focus groups, and online focus groups produced in-depth data. Nevertheless, following the comparison of the data sets the interviews had slightly more breadth and in-depth detail around the outcomes. This difference may be due to the discrepancies in sample sizes between the three data collection methods, which could have directly influenced data saturation (223-226). The interview dataset achieved saturation but the focus group datasets did not (See Chapter 4 section 4.4.2.5). There were low participant numbers in the focus groups, especially in the online focus groups but it is important to note that although neither the face-to-face focus groups nor the online focus groups achieved saturation, both datasets produced a similar range of outcomes.

The literature, in general, suggests that interviewees will produce greater depth of information about their beliefs and attitudes compared to focus groups (227). Focus groups explore the nature of jointly produced data and may highlight the similarities and differences between participants in the ensuing discussions (95). Barbour reports that in the past researchers used focus groups to develop items

for inclusion in surveys, generally for market research purposes (108). This legacy still prevails today with some researchers preferring to rely on interviews to produce in-depth data although, as Barbour points out, generating items for a questionnaire and in-depth data may not be mutually exclusive (108).

As the design of my primary research was to collect data through face-to-face and online focus groups, I chose to review existing papers that have reported similarities and differences between these two methods (see Chapter 3 for the results of this review). It is to be noted that to-date studies have been undertaken to compare the types of data elicited through different qualitative data collection methods (99, 114, 116, 128-131) such as comparing face-to-face interviews and focus groups (99, 129, 228). In accordance with my research findings Stokes, who compared face-to-face interviews with face-to-face focus groups, reports that the interviews produced more depth and detail about the issues along with subtleties of attitude and they identified all the main issues (228). In contrast to my findings, Stokes reports that the focus groups produced greater breadth. Guest also compared face-to-face interviews and face-to-face focus groups and found that both data collection methods produced very similar lists of issues which are comparable to the findings of this research where all datasets produced a similar range of outcomes (129). Lambert advocates the use of both face-to-face interviews and focus groups to provide greater interpretation of the phenomenon and to enhance the trustworthiness of the findings (99). The design of my research follows Lambert's suggestion of collecting qualitative data by different methods but differs because I chose to compare three methods of

qualitative data collection (interviews, face-to-face focus groups, and online asynchronous focus groups) rather than two. Lambert recommends conducting focus groups first to understand the range of issues, followed by interviews to elicit detailed descriptions of the issues. Lambert does however acknowledge that further research in this area is required (99). A comparison of individual interviews and online forums reported by Seale suggests that interviewees are less likely to disclose sensitive information compared to participants in online forums (121). They suggest that the presence of the interviewer might influence the way a participant wants to portray themselves, which in turn may result in responses not true to a participant's real beliefs or feelings. This contrasts with the data elicited in the re-analysis of the PEGASUS interviews where participants did disclose sensitive information. Seale suggests that online forum posts may be a valuable source of information when researching sensitive topics because participants may offer emotional support and shared experiences, and the perceived anonymity may make participants feel more comfortable about sharing sensitive details (121). The limitations of using existing online posts include the inability to probe for deeper explanations and the uncertainty of who is actually taking part in the discussion. Any available demographic and clinical information will in general, be self-disclosed by the participants rather than confirmed by a clinician. By conducting online asynchronous focus groups, I was able to delve deeper into participants' responses. Although I conducted online focus groups as opposed to viewing online posts, there was disclosure of sensitive data particularly in online focus group 1. Additionally, as suggested by Seale, I observed the online participants offering support and advice to each

other (121). Support and advice amongst the participants also happened in the face-to-face focus groups. Recruitment took place through social media so I still faced the problem of participant self-disclosure regarding clinical status and eligibility (see section 6.6 for further discussion on this).

Brunton compared outcomes in neonatal research identified in a quantitative review to those identified in a qualitative review (229). They found that 18 outcomes identified in the qualitative review were not identified in the quantitative review, whereas just three in the quantitative review were not identified in the qualitative data. The qualitative data reported wider psychological issues and the quantitative data produced biological health-related outcomes synonymous with randomised controlled trials. This is perhaps not surprising given that the quantitative review included clinical trials where clinical and/or academic staff most likely chose the outcomes.

These comparisons illustrate the diversity of opinions when it comes to the range of outcomes identified by different approaches to data collection (quantitative and qualitative). Brunton's paper supports the premise of this thesis that qualitative research is the preferred data collection option when aiming to elicit and understand treatment outcomes that are important to patients (229).

Using qualitative data collection methods to elicit patient views on outcomes for inclusion in COS prioritisation exercises is a relatively new area with little existing research to call upon. As previously stated in section 6.2.2.1 a closely related area of research is eliciting patient views in the development of PROs. A recently published paper by Humphrey aimed to compare patients' perspectives on ankylosing spondylitis through three different data collection methods: 1) Concept elicitation interviews, 2) group concept mapping and 3) a social media review (230). Of the range of outcomes identified by Humphrey, just nine out of 26 (35%) arose in all three methods with the most, 23/26 (88%), identified in the social media review. The social media review was the only medium to identify sensitive and socially embarrassing issues. Regarding the depth of detail, Humphrey found that the interviews produced the most in-depth responses (230). However, the interviews did not identify eight of the final list of outcomes and, had the other methods not been included, these outcomes would be missing. Humphrey recruited participants with the aim of achieving conceptual saturation but the results suggest that the concept elicitation interviews did not achieve saturation. As part of her study, Humphrey conducted twelve interviews but only 69% of the outcomes were identified from these. This is in contrast with the results from this study where the interviews elicited the greater number of outcomes. Both this study and Humphrey's agree that interviews produced the most in-depth data. Humphrey recommends combining all three methods to produce the best results and concludes that although there is variability in the data produced between methods there is minimal misrepresentation of the participants' views. The methods used to elicit data from each of the three

methods differed and this may be why there is an inconsistency in the number of outcomes identified. The concept elicitation interviews used a semi-structured approach. Using an *a-priori* protocol listing the relevant information to be extracted data were extracted from social media posts and the participants in the group concept mapping exercise were asked to list symptoms. Use of similar topic guides for the interviews, face-to-face focus groups and online focus groups in this research ensured consistency and comparability across the datasets.

6.3.3. How the findings relate to the current burns literature

Chapter 5 reported the findings from the re-analysis of the interviews conducted as part of the PEGASUS feasibility study and the findings from the primary collected data using face-to-face focus groups and online asynchronous focus groups. Six outcome domains were interpreted from the data: 1) features of the scar 2) sensation of the scar, 3) mobility movement and function, 4) psychological well-being, 5) returning to a normal life and 6) treatment regime. As the analysis progressed, it became clear that there was a link between many of the outcome domains and outcomes. For example, there is a link between the appearance of a scar and psychological symptoms such as depression.

How the scar looks and feels was important to all of the participants and discussions of these features were present in all of the data collection methods.

For example, participants reported how they would like to reduce the colour and/or reduce the height of their scars. For a few of the participants, the location of the burn on their body, how they felt about it, and how they accepted the burn injury were linked, although these subjective opinions are not reflected in the wider literature. Those participants who stated they were not bothered by their burn injury can be explained as a defensive mechanism, wanting to put on a brave face or not wanting to show their vulnerability (231). Regarding pain and itch, there was no clear agreement between the participants about these symptoms; some attributed the itchiness and pain to the treatments whereas others found that the treatments helped to ease them. This finding suggests that the nature of pain and itchiness is subjective and everyone experiences it in different ways and in different circumstances. McGarry (232) and Perez-Boluda (233) have linked these sensations to mental health and quality of life. Given that pain from a burn injury can be experienced for more than three years post injury and that pain is influential upon the reported quality of life, Perez-Boluda recommends that patients are involved in the improvement of assessment and treatment of pain as a symptom (233). Likewise, given the effect itchiness can have on patients' lives, McGarry suggests there is a need for further research into itchiness and mental health (232). Needless, to say the improvement of scar features and scar sensations are outcomes of importance to patients.

Treatment for a burn injury can be intense, lengthy and multi-faceted and this can prove to be problematic and burdensome for patients especially when they have multiple morbidities (104, 234, 235). In line with the findings of Martin (231),

Ripper (234) and Mackie (103), this study found that patients often rely on the support of others to help them with their treatment regime; getting into pressure garments, massage and creaming. Participants discussed the amount of time needed to make frequent trips to the hospital, which in many cases was a substantial distance from home. Due to their injuries, some participants were unable to drive and found themselves dependent on friends and relatives to take them to appointments (103). Having to rely on others weighs heavy on some participants' minds. They talk about being grateful for the help but they also talk about feeling guilty because of the strain they are putting on their friends and relatives (104, 236). It is suggested that this dependency on the help and support of others can have a negative effect on patients, making them revert back to a child/parent relationship unable to make their own decisions (236). On the other hand, the support of others can empower patients to persevere with treatment and to move on with their lives (104, 236). Many participants reported the extra burden of uncomfortable pressure garments but some talked about pressure garments providing them with comfort, protection, and security such as protecting the injury from further harm or from sunlight, help with mobility, and psychologically shielding them from looking different to the outside world (231, 234, 237).

Most participants talked about returning to a normal life. In agreement with Johnson's findings, the majority of participants accepted that normal life post-accident would be different because some aspects of their life would need to be adjusted to take into account the injury (236). There were some participants who

hoped to return to their pre-accident life (237). Mobility, getting around, being able to take part in favourite leisure activities and returning to work were key to rehabilitation and returning to a ‘normal’ life. My findings that some burns patients will return to the job they had before the accident, some to different jobs, and others will decide not to return to work support the findings of Mackey (103). A return to work may be dependent on patients’ psychological health, the support of family, friends and their employer. Employer support cannot be under estimated; the support, or lack of support, from an employer can mean the difference between a patient returning to work and not returning (103, 236). Mobility or range of movement, returning to work and leading a ‘normal’ life were important to the participants.

Psychological symptoms can have a big impact on other burns outcomes and vice versa. Due to the nature of a burn injury, the guilt felt by many following the accident and feelings of uncertainty about the future means that it is not uncommon for burns patients to experience depression or PTSD (100, 238). Additionally, the intensity of pain and itching can also affect a patient’s mental health (232, 233). As previously described, many participants felt that the psychological symptoms they experienced following their burn injury were worse than the physical injuries (101, 102, 239). If patients are to move on with their rehabilitation and to recover from their psychological symptoms, they may need the support of family, friends and HCPs. The psychological effects of a burn injury have a huge impact on individuals and their recovery and are important

aspects for consideration when thinking about the scar management outcomes that are important to patients.

The interviews carried out as part of the PEGASUS feasibility trial aimed to understand the priorities and perspectives of burns patients and to compare the findings with concepts captured in burn-specific Patient Reported Outcome Measures (PROMs) (105). The outcomes elicited were organised into eight outcome domains: Scar characteristics and appearance, movement and function, scar sensation, psychological distress, adjustments and a sense of normality, body image and confidence, engagement in activities, impact on relationships and treatment burden.

The PEGASUS study dataset, of which the interviews with adult burns patients were re-analysed for this research, also included interviews with parents and carers of children who had suffered a burn injury. The adult dataset and the parent dataset identified similar sets of outcomes (105). However, the parental dataset had subtle differences in emphasis for example the impact of a child suffering a burn injury can place great strain on the rest of the family when one parent stays at the hospital with the injured child, which may be for a considerable length of time. Adult patients were concerned about the additional strain they were placing on the friends and/or relatives who were taking care of them.

There are subtle differences between the PEGASUS findings and the findings from this research, the OSCAR study. There is a slight difference in how scar characteristics and general appearance are categorised. Scar characteristics and general appearance form the overall domain reported in the PEGASUS paper whereas general appearance is an outcome under the domain scar features in my coding structure. Nevertheless, the findings are similar in that participants talk about different aspects of their scar depending on the context of the question they are answering. Such as, when asked about what they would like to achieve from their pressure garment treatment they relate their answers to specific scar features, wanting the colour to fade or wanting the height of the scar reduced. Whereas when talking in general terms about their injury participants would refer to the overall appearance of their scar. Additionally, both findings report that the location of the scar can affect how a participant feels about its appearance. In concordance with my analysis, the PEGASUS paper reports that participants often talked about movement and function interchangeably. However, the PEGASUS paper suggests that function is perhaps more important to participants than movement whereas this distinction is not made in my findings. In my discussion of scar sensation, there is more detail around itch and sensitivity compared to the discussion of this domain in the PEGASUS findings. To conclude, although there are subtleties in interpretation between the two studies, they have both identified a similar broad range of outcomes that are important to patients.

The development of a COS for burn care is currently underway. As part of the development process Young plan to undertake semi-structured interviews with burns patients over the age of 10 and with parents of children of any age who have suffered a burn injury (240). They aim to identify a long list of patient outcomes through the interviews to supplement those identified through a systematic review. They will take these outcomes forward to a prioritisation exercise (Delphi survey) and a consensus meeting. As stated previously the PEGASUS and OSCAR research teams are keen to see transparent reporting of data and the efficient use of resources therefore the findings from the PEGASUS and OSCAR studies have been provided to Young and the team.

6.4. The added value of using qualitative research to elicit outcomes that are important to patients in COS development

Qualitative data can provide in-depth information from a patient's perspective on what it is like to live with a health condition and what aspects are important for their treatment and recovery and why (53, 66, 82). The importance of this for a COS development exercise is:

1) To make sure the final COS is relevant to all stakeholders including patients;

2) To provide information on outcomes not available from systematic reviews of studies;

3) To identify gaps in existing COS where patients have not been included;

4) To identify why outcomes are important to patients;

5) To provide an understanding of the language used by patients when describing their illness in order to feed this effectively into prioritisation exercises (53).

Additionally, patients' descriptions can be used to validate the reasons why outcomes are important should disagreements arise during consensus meetings (53, 65, 241). Prior to carrying out qualitative research, there are some considerations to take into account for both participants and researchers, especially when dealing with sensitive topics. These include the close monitoring of participants to ensure they do not become upset when talking about sensitive issues. A distress pathway should be in place before the commencement of data collection outlining the steps to take if such a situation arises. Likewise, a debrief session for the researcher is advised so they can discuss with a colleague any upsetting occurrences which may have arisen during data collection. (See Chapter 4: Methodology and methods, section 4.4.3.3.).

Primary qualitative research with patients can feed into a COS development exercise in ways that patient input through PPI and the ability to suggest additional outcomes in a Delphi survey cannot. PPI participants contribute to the research process by making decisions that will shape the way the research or COS development are conducted whereas qualitative research with patients as research subjects collects data to answer specific research questions, such as

what outcomes are most important to patients (242). Qualitative research can provide explanations on why outcomes are important to patients, this data is useful if there is disagreement amongst stakeholders on which outcomes to include in the final COS. Qualitative data can identify gaps in existing COS where qualitative research with patients was not included. COS developers can compare the outcomes generated through qualitative research with other sources of data and be confident that all potentially relevant outcomes are included in the first round of the Delphi and this can reduce the total number of Delphi rounds required. Finally, qualitative research may be the only suitable method of involving certain groups of patients in COS development, such as those with dementia or learning difficulties.

The collection of qualitative data can be time-consuming and costly especially if a COS development exercise is time and resource limited. The use of pre-existing qualitative data to inform a long list of outcomes important to patients may be a practical alternative. Using pre-existing qualitative research may not necessarily be quicker to complete, but it will not incur the costs associated with organising and running interviews and focus groups. Brunton carried out a synthesis of existing qualitative research in the development of a COS for neonatal care (243) (see section 6.2.2.5). Likewise, Webbe plan to carry out a review of existing qualitative research for their COS in neonatal medicine (244). Re-analysis of existing qualitative interviews was carried out by Rankin in their study to develop a COS for polypharmacy in older people in primary care (165).

Rankin reports that this method identified 22 (41%) of the 54 outcomes identified in the first phase of the COS development.

In their protocol, Webbe lists a number of advantages to using existing qualitative work (244). These include the avoidance of duplicating work, a diverse range of views may be identified, participants' time is not wasted, data from a range of qualitative data collection methods can be incorporated, efficiency, and the identification of different outcomes to those already measured. They identified two disadvantages; the data are limited to that which the original research addressed, and the stakeholders are removed from the data.

A systematic review of qualitative literature by Hashem aimed to identify patient outcomes on discharge following a critical illness to inform the development of a COS for ICU survivors (245). The authors mapped the findings of the included studies onto existing Patient Reported Outcomes Measurement Information System (PROMIS) descriptors such as satisfaction with life and physical health. Although reporting success in producing a potential list of patient important outcomes, mapping data into an *a priori* framework may inhibit further interpretation of the data thereby missing potentially relevant outcomes.

Whichever qualitative method is used, primary research or secondary analysis of existing qualitative work, there is no guarantee that the outcomes identified as important by patients will be included in the final COS. The involvement and participation of patients throughout the development of a COS may help to minimise this risk. The inclusion of patients in a consensus meeting can be challenging and has raised the issue of whether it is practical to hold meetings with both HCPs and patients when making decisions about which outcomes to include, or whether it is preferable to hold separate meetings for HCPs and patients. The concern with joint meetings is that patients may feel undermined, intimidated by the HCPs and may feel pressured to conform and therefore will not express their own views. This debate is ongoing and further research into this is required (53). Whether consensus meetings are held separately or together to ensure every participant is treated fairly and is able to have their say, careful facilitation is required and consideration of the patients' needs is important (53, 217).

Based on the evidence from this research, it is recommended, when seeking a list of outcomes that are important to patients, to conduct primary qualitative face-to-face data collection using interviews. It provides the opportunity for COS developers to purposively sample for participants who will be able to provide insight into patients' perspectives on which outcomes are important to them, and to produce a subject-specific topic guide to aid the discussions. Interviews elicited data on more outcomes than face-to-face focus groups and online focus groups and provided more in-depth data around outcomes, but it is important to

qualify this finding. Firstly, a very similar range of outcomes was identified in all of the datasets; secondly, face-to-face and online focus groups did not achieve saturation (see Chapter 4, section 4.4.2.5). This was possibly due to low participant numbers. Had a higher number of participants been recruited and saturation achieved the findings may have been different. Lastly, the resources available to COS developers may dictate the qualitative data collection methods they use. The choice of any of these methods could be acceptable given that both the face-to-face focus groups and online focus groups identified a similar broad range of outcomes to those identified from the interview dataset and they provided in-depth data.

6.5. Resources

The Database of Instruments for Resource Use and Measurement (DIRUM database) provides validated questionnaires to measure such things as hospital attendance costs, length of stay in hospital, social care costs and symptoms and symptom management (246). In the main, these questionnaires are for the use of health economists involved in economic evaluations in clinical trials. Currently, there are no guidelines or instruments to collect details of the resources required to run qualitative research.

Throughout this study, I have documented details on the resources required. These include the number of days taken to recruit participants to the study and

the number of days taken to collect and analyse data. I have used this information to calculate costs for all aspects of the primary research. All research is different with varying requirements so this information is not definitive and is provided only as a guide for future researchers to consider when planning COS exercises involving qualitative research with patients.

The conclusion of this thesis is that interviews generate more in-depth data and the recruitment of participants was more straightforward. Whereas recruitment to the focus groups, especially the online focus group was more difficult. Given that time and resources can be limited in a COS development details on alternative qualitative data collection methods are provided and show that they too can be acceptable for eliciting pragmatic data on outcomes important to patients. Details on the resources required to carry out each of the included data collection methods are included to help researchers decide on which method(s) to use in their COS development. The interviews were the most expensive to run and the online focus groups the cheapest.

As long as time and resources allow this research recommends that interviews are the best qualitative data collection method to use in COS development and the depth of data elicited can outweigh the associated resources. However, it is ultimately individual COS development teams that will need to decide if obtaining depth of data, which can inform the inclusion of patient important outcomes and the reasons why they are important, outweigh the time and costs involved in conducting interviews.

In addition to the resources required for qualitative research in COS development such as time and money, it is important to consider the skill set of the researcher(s). For example, if this research were to be duplicated it would require someone with experience of setting up websites, but it is possible to gain the skills and knowledge required to build and develop a website in a relatively short space of time, (section 6.6 outlines my experience of creating a website). The traditional skills of a qualitative researcher would also be required including the ability to facilitate both online and face-to-face focus groups. What is different, however, is that the facilitator of an online asynchronous focus group may be required to access the forum at least once per day for the duration of the discussion (247). Different qualitative data collection methods will require a different number of facilitators, for example, in this study one facilitator was required per interview and per online focus group. However, two were required for the face-to-face focus groups to help with the consent process, facilitation and notetaking (107, 155).

Finally, although not within the scope of this research, future researchers should consider the importance of involving patients and the public as research partners. Patients and the public can offer valuable advice and insight into the co-design of research by offering their perspectives on research priorities, study design considerations, patient information, and recruitment strategies. Clarification of patients' roles early in the research process is good practice as is

the clear reporting of those roles in resulting publications. Patient involvement should be a continued partnership whereby the patients are also involved in study management, interpretation and dissemination of results, and crucially in reporting results back to patients. (53, 65, 248).

6.6. Reflections on my research experiences

Prior to starting this Ph.D. I worked as a trial coordinator for several years. As hoped, my knowledge of the processes, procedures and regulatory requirements associated with health-related research was a real advantage when designing my own primary research study. All aspects of this research have taught me the importance of being methodical and consistent and the benefit of good planning, such as well-planned data extraction forms and detailed outlines when writing.

Regarding data collection, I was a complete novice and to facilitate focus groups was quite daunting. I attended specialist focus group training and received excellent advice from my supervisory team but it was challenging putting all the advice and training into practice in a real focus group situation (89). Given the fast nature of the conversations, picking up aspects of the discussion for further clarification was particularly difficult as the topic of conversation could change rapidly. To help with this when planning the focus groups my supervisors suggested having a summing up session with the participants. Summing up happened after discussion of each of the three topic areas, and relevant

information written on the whiteboard or flipchart for everyone to see. This helped to mop up any outstanding issues from the participant perspective and provided me with an opportunity to ask further questions. This worked well and I would adopt this method again, where appropriate, in any future face-to-face focus groups. The face-to-face focus groups generated relevant and appropriate data and this was thanks to the help from my supervisors who acted as co-facilitators.

The online focus groups presented a different challenge as neither myself nor my supervisors had experience in this area. I studied the literature about online focus groups and used this information to design my own process and procedures. I built my own study website from which participants could access the discussion. Due to a lack of funds, I was unable to outsource the build and design of the website. A friend and colleague provided help and assistance in the early stages but as the website evolved, I was able to address any design and update issues myself. This is something I would never have considered doing if funds were available and it is a skill I am proud of achieving. I regard the website and online discussions as a success – all participants were able to log in, read and post messages without any reported difficulties.

Analysis of qualitative data was new to me and I initially found the volume of data difficult to handle. After basic training, I coded and sorted the data using NVivo 11 software. However, I often found that I reverted to reading and coding

by hand on printouts of the transcripts. I felt that this process made me feel closer to the data and able to see the context more easily by looking at a complete transcript rather than a page or section at a time on the screen (182, 249).

Overall, my Ph.D. journey has been a positive and rewarding learning experience. I come away from it with a deeper understanding of the research process and of my own strengths and weaknesses. The highlight of my research has been meeting the participants, listening to what they have to say, learning about burn injuries, and contributing to the knowledge base around using qualitative methods with patients in COS development.

6.7. The strengths and limitations of this research

The review of patient and carer participation and the use of qualitative methods in COS development (Chapter 3) is, as far as I am aware, the first review to focus on the use of and the reporting of qualitative methods in COS development. It has highlighted the poor reporting of the methods used; none of the included papers reported an underlying methodology and some reported the numbers of participants but did not report how many were HCPs, how many were patients and how many were carers. The review concluded with the need for more research comparing different qualitative data collection methods and a

table of recommendations for reporting qualitative research in COS development was provided.

Exclusive use of the COMET database in this review may have led to the omission of some relevant papers. I tried to address this issue by carrying out reference searches on the included papers. Another limitation of this work is that the scope of the review was to evaluate patient and carer participation in COS research only and not patient and public involvement in these exercises.

To my knowledge, no previous review has examined the reported similarities and differences between the types of data collected using online and face-to-face focus group methods (Chapter 3). Data were compared against the following criteria: sampling and recruitment, participant characteristics, analytical approach, depth of data, participant interactions and the required resources. Similar to the findings reported for the review in Chapter 2, this review found that the reporting of the use of qualitative methods was inconsistent making it difficult to draw substantive conclusions. Using Traditional Pearl Growing methodology to search for papers was a novel approach to searching for papers. Given that papers matching the aims of the review were likely to be across a wide range of disciplines, the Traditional Pearl Growing methodology was considered an appropriate approach. However, the process was not as efficient as hoped and the searches may have missed some relevant papers.

The primary research (Chapter 5) is, to my knowledge, the first to compare three different qualitative data collection methods: interviews, face-to-face focus groups and online asynchronous focus groups with a view to eliciting treatment outcomes that are important to adult burns patients. This is also the first study to provide a summary of the resources associated with each of the data collection methods and a list of generic cost incurring items. It is hoped that this information will be a point of reference for future researchers planning to use qualitative methods in their COS development process.

Recruitment to the face-to-face and online focus groups proved difficult. The personal and sensitive nature of the topic may provide one possible explanation (250, 251). Recruitment to the interviews was straightforward and therefore, a more likely explanation is that the OTs were extremely busy and found it challenging to identify potential participants for the face-to-face focus groups. My lead supervisor chased the OTs on several occasions to remind them about recruitment for this study. Recruitment to the online groups was difficult, many people expressing an interest in taking part in the online groups were subsequently not contactable or not interested when they received further details about the research. Currently very little guidance on the best ways to recruit participants to online focus groups and to-date studies have used a variety of methods. For example, advertising a study on the website of an appropriate support group (119, 122, 128, 145) is one approach, and an option that I used. The recruitment of participants from an existing source i.e. from an earlier phase of a study (127), from hospital treatment lists (111) or from those who are unable

to attend a face-to-face focus group (98). Although unsuccessful, I attempted to recruit from those unable to attend the face-to-face focus groups when recruitment to the online groups was slow. Prior to recruitment, clinicians confirmed the health status of the interview and face-to-face focus group participants. Online participants self-disclosed their health status and due to anonymity, it was not possible to confirm their eligibility.

The reasons for the recruitment difficulties to the face-to-face and online focus groups remain unclear, although adopting more approaches as illustrated above may have improved the numbers recruited. Three participants to the face-to-face focus groups dropped out on the day of the group due to personal circumstances. I received verbal comments from two potential face-to-face participants who declined to take part, one because they were uncomfortable talking about their burn injury in a group situation and the other because of the lack of financial incentive. It was difficult to ask potential online participants why they did not want to take part because the only contact details I had were email addresses and they did not respond to any of my emails. Two recruited online participants failed to log into the discussion forum despite reminders and encouragement to do so. With so little feedback, it remains unclear why some potential participants declined to participate.

Occupational therapists in Birmingham, Swansea, and Bristol identified potential participants for the face-to-face focus groups following the study inclusion and

exclusion criteria. This provided a geographical spread of participants across the UK. Recruitment to the online groups was through UK online burns websites and social media accounts and with the intention of providing a geographical spread of participants but due to the anonymous nature of the focus groups, it was difficult to tell if this was achieved.

When no new outcomes were interpreted from the data saturation was judged to have been achieved. As separate datasets, the focus groups may not have reached saturation. However, when compared to the interview dataset it became apparent that the focus groups generated the majority of the outcomes identified in the interview dataset (28 out of 33 outcomes were interpreted in all datasets). The literature suggests that core themes can be identified with low numbers of participants (224). Therefore, I am confident in my findings that key outcomes were identified in all datasets.

In this study, all three data collection methods generated similar outcomes and the differences between the depth of data and the characteristics of the sample were modest. However, the low numbers of participants in the face-to-face focus groups and the online focus groups may not be a true representation of the types of data and participant involvement that can be elicited by these methods. For example, the participants were less forthcoming in online focus group 2 compared to online focus group 1. It is therefore difficult to know whether participants in any further online focus groups would have behaved in the same

way. See the OSCAR study results (Chapter 5) for a detailed discussion on the similarities and differences between the data collection methods in each of the datasets.

With online focus groups, there is the danger that the discussion may turn into a question and answer session with participants replying directly to the moderator rather than discussing with the other participants. Unfortunately, this proved to be the case in the second of my online focus groups where the participants were responding directly to my questions rather than acknowledging and addressing each other (148). This may have been because there were only two participants in the group. In contrast, as suggested by Walsh participants in online focus group 1 generated interaction between themselves by responding and empathising with each other (155).

I was blinded from the PEGASUS feasibility work so as to limit any potential influence on my primary data collection and analysis and the re-analysis of the interviews (105). However, due to time constraints, my analysis of the interview data took place before the primary data collection. I was aware that this may influence my primary research such as leading me to look for or elicit something specific in the focus groups because I knew it was in the interview dataset or trying to force focus group data into interview codes. Therefore, I bracketed my work on the interview dataset whilst I approached the focus group data collection and analysis with fresh eyes. In qualitative research, bracketing is used to try to

mitigate the impact any prior knowledge may have on the delivery and interpretation of the research (88, 252).

The findings of this research are a reflection of the views of this group of participants and my interpretation of these narratives. There was a relatively diverse sample across the three different data collection methods, which may be transferable to the wider burns population. They offer an insight into the use of qualitative methods to elicit patient experiences and views of preferred scar management outcomes.

6.8. Recommendations for future research

In order to further existing knowledge on the use of qualitative data collection methods with patients as part of a COS development exercise, future research should concentrate on the following aspects.

Given the small number of participants recruited to the primary part of this research, further research with burns patients is required. This research should compare the differences and similarities between the qualitative data produced by each data collection method (interviews, face-to-face focus groups, and online focus groups) in relation to eliciting and understanding outcomes that are important to patients. Future research should try to accommodate the views of a

diverse sample of participants as their views may differ, such as participants from different sociodemographic backgrounds (53, 65). Online focus groups should be functioning, engaging, empowering and have an impact (253). As the results of my online focus groups are inconclusive, further research is required to evaluate the potential of using online synchronous or asynchronous focus groups as either, a standalone qualitative method or in conjunction with other qualitative methods.

Review and synthesis of existing qualitative research may help researchers to establish whether relevant patient important outcomes are identifiable and provide understanding of why the outcomes are important. To date, however, there is no evidence or precedent for using the synthesis of existing qualitative research for these purposes. Further research in this area will help COS developers to assess whether using existing qualitative research may be a viable alternative to collecting primary data in a resource-limited COS development process.

Table 6.1 is a summary of recommendations for COS developers to consider when choosing to include qualitative data collection methods to elicit outcomes important to patients.

Table 6.1 Summary of recommendations for COS developers wishing to incorporate qualitative data collection methods with patients in the development of a COS

Reporting recommendations for qualitative research in COS development (Chapter 2)
The methodological approach used
Research aims and relationship with broader COS development process
Sampling approach
Type of data collection methods (interviews, focus groups, combination); content and derivation/justification (e.g. topic guide)
Analytical approach and justification
Sample characteristics and participant number
Findings related to outcome domains (concordant with research aims)
Approaches to ensuring rigour (e.g. multiple perspectives on data, respondent validation) and consider reflexive content
Discuss the strengths and limitations of approaches
When using a combination of face-to-face and online qualitative data collection methods for the purpose of comparability (Chapter 3):
Purposively sample participants against the same criteria for both datasets
Develop similar topic guides for both data collection methods
Use the same analytical approach for both datasets
Things to consider when setting up and running online focus groups (Chapter 4)
Check for ethical requirements for conducting online focus groups
Decide whether to use synchronous or asynchronous online groups

If using asynchronous online groups decide how long the group will run for
If using synchronous decide which medium to use (e.g. Skype, text based)
Decide how many facilitators you will need. (If synchronous, it may take two to monitor the quick moving discussion).
If using a text based medium which is readily available build a study website and discussion forum
Recommendations applicable to all qualitative data collection methods (Chapter 6)
Decide on and use an appropriate qualitative methodological approach (e.g. interpretive description)
Involve patients as research partners from the beginning.
If dealing with a sensitive topic, set up a distress pathway to be followed if a participant becomes upset during the interview/focus group
Contact participants two days before each interview/focus group
Ensure experiential questions are included in the topic guide. (Patients find it difficult to relate to direct questions about outcomes)
Assess the research teams available time and resources and choose data collection methods accordingly

6.9. Conclusion

In conclusion, this work has addressed important topics related to qualitative research methods and COS development. The findings demonstrate that, to date, there has been limited participation of patients in the development of a

COS and of those that have, only a small proportion were involved in qualitative data collection methods to elicit patient outcomes that are important to patients.

This thesis has compared the data collected by three different qualitative methods (interviews, face-to-face focus groups, and online asynchronous focus groups) with a focus on eliciting outcomes from adult burns patients receiving pressure garment therapy. Although there was a minimal number of face-to-face focus groups and online focus groups, all datasets produced a similar broad range of outcomes. Consequently, if COS developers are only interested in the potential range of outcomes to take forward into a consensus exercise then any of these qualitative data collection methods could be suitable.

It is important that a COS is relevant to all stakeholders including patients. This research has highlighted the benefits of using primary qualitative research with patients in COS development. COS development can be time and resource limited, therefore, it is hoped that the details about the associated time, resources, and costs of each of the included methods will encourage developers to include qualitative research when developing an initial list of outcomes.

This work provides a valuable contribution to the growing uptake and implementation of COS in effectiveness trials. There is currently no research on the value and the practical implications of using different qualitative data

collection methods to elicit outcomes important to patients. What remains unknown is how outcomes identified as important to patients through primary qualitative data collection contribute to the final COS. Only by COS developers embracing and valuing the contribution that qualitative primary data collection with patients can make to a COS will this become clear.

APPENDICES

Appendix 1 – S1-Planned and ongoing studies (correct as Aug 2015)

1. Alam M, Maher I, Sobanko J, Cartee T. Core Outcome Set for the Appearance of Facial Aging.
2. Azuara-Blanco A, Hogg R, Boylan NLJ. Development of core outcomes measures for diabetic retinopathy interventions.
3. Azuara-Blanco A, Hogg R, Chakravarthy U. Development of core outcome measures for age-related macular degeneration (AMD) interventions.
4. Azuara-Blanco A, Ramsay C, R I. Development of core outcome measures for glaucoma interventions.
5. Beeckman D, Kottner Charite J. Developing a Core Outcome Set for Incontinence-Associated Dermatitis (IAD) Research.
6. Benstoem C, Moza A, Stoppe C, Goetzenich A, Autschbach R. Development of a core outcome set (COS) for non-minimal-invasive on-pump cardiothoracic clinical trials.
7. Birchwood M, Calvert M, Keeley T, Pinfold V, Davies L, England E, et al. PARTNERS 2: Development of a core outcome set for use in mental health trials involving people with schizophrenia or bipolar disorder in a community based setting.
8. Blazeby J, Brookes ST, Avery K, McNair AGK, Whistance RN. Development of core outcome sets for informed consent and clinical trials of colorectal surgery.
9. Byng R, Shaw J, Stirzaker A, Stewart AK, Quinn C, Lennox C, et al. Engager 2: Developing and evaluating a collaborative care intervention for offenders with common mental health problems, near to and after release.
10. Cartee T, Maher I, Sobanko J, Alam M. Core Outcome Set for Facial Structure and Function Post-Skin Cancer Excision.
11. Chazapis M, Moonesinghe R, Kamming D. Core Outcomes in Regional Anaesthesia (CORE).
12. Clark M, Samuelson E, Schaeffer M, Alam M. Core Outcome Set for Acne Scarring.
13. Colavincenzo M, Schlessinger D, Iyengar S, Samuelson E, Schaeffer M, Alam M. Core Outcome Set for Hair Loss/Non-Scarring Alopecia.
14. Costa M, Fernandez M, Tutton L, Khan U, Jain A, Kelly M, et al. A core outcome set for comparative effectiveness research in open lower limb fractures.
15. Coulman K, Owen-Smith A, Blazeby J, Welbourn R, Andrews R. the patient perspective of living with surgery for morbid obesity: Creating a patient "core" outcome set, and investigating ways to improve follow-up care.

16. Davidson B, Gurusamy K, Simillis C. Development of core outcome sets in clinical trials comparing treatments for the management of colorectal liver metastases and liver resection.
17. Denniston A, Calvert M, Murray P, Moore D, Mathers J, Blazeby J, et al. Defining a Core Outcome Set for Efficacy Trials in Adult Patients with Posterior Segment-Involving Uveitis.
18. Devane D, Smith V, Boylan G, Alfirevic Z, Kenny L. Developing a core outcome set (COS) for intrapartum fetal assessment.
19. Devane D, Smith V, Daly D, Lundgren I, Eri T, Begley CM, et al. Salutogenic Intrapartum Core Outcomes (SIPCO): Identification of a minimum dataset using an international eDelphi consensus process.
20. Devane D, Smith V, Dunne F. Developing a core outcome set (COS) for clinical trials in GDM.
21. Devane D, Smith V, Kenny L. Developing a core outcome set (COS) for clinical trials in intrauterine growth restriction.
22. Duffy J, Hirsch M, Davis C, Farquhar C. Developing a Core Outcome Set in Endometriosis.
23. Duffy JMN, McManus R, Ziebland S, Khan K, Altman DG, Fitzpatrick R, et al. Developing a core outcome set for hypertensive disorders in pregnancy.
24. Duncan-Millar J, Ali M, Pollock A, van Wijck F. Standardisation of Outcome Measures in Trials of Upper-Limb Rehabilitation after Stroke.
25. Egan A, Smith V, Devane D, Dunne F. Developing a core outcome set (COS) for clinical studies of prepregnancy care for women with pregestational diabetes mellitus.
26. Fabricius M, Heer R, Pickard R, McColl E. Development of core outcome measures for clinical trials in advanced prostate cancer.
27. Fernandes RM, Offringa M, Van der Lee JH, Klassen T, Hartling L, Plint A. Outcomes in clinical trials of bronchiolitis.
28. Forster A, Young J, Brown L, Crocker T, Clarke D, Clegg A. Core outcome set relevant to (physical rehabilitation with) frail older people (in care homes).
29. Gagnier J, Morgenstern H, MacEachern M. Core outcome measures for rotator cuff disorders.
30. Glenny A, Worthington H, Brocklehurst P, Taylor J, Riley P, Walsh T. Core outcome measures and selective outcome reporting in randomised controlled trials of oral medicine.
31. Glenny A, Worthington H, Walsh T, Burnside G. Core outcome measures and selective outcome reporting in randomised controlled trials for the prevention and treatment of periodontal disease.

32. Goncalves ACV, Samuel D, Demain S, Marques A, Cruz J. Development if a core outcome set to evaluate physical activity in people with dementia.
33. Hall D. Developing a global consensus on outcome measures for clinical trials in tinnitus: the COMiT initiative (Core Outcome Measures in Tinnitus).
34. Hall N, Ross A. Establishing a core outcome set (COS) for infants born with gastroschisis.
35. Harrop E. Supporting people bereaved through advanced illness: A systematic review of the evidence and development of a core outcome set for bereavement research in palliative care.
36. Hart N, Connolly B, McAuley D, Gulliford M. Development of a core outcome set for trials of rehabilitation following critical illness.
37. Iyengar S, Samuelson E, Schaeffer M, Alam M. Core Outcome Set for Rosacea.
38. Kaiser U, Schmitt J, Kopkow C, Sabatowski R. Validation and application of a core set of patient-relevant outcome domains to assess the effectiveness of multimodal pain therapy.
39. Kapadia M, Offringa M, Balasingham C, Joachim K, Cohen E, Mahant S, et al. Core set of outcomes for children with neuro-disability and gastrostomy tube dependency: A tool of standardized outcomes for clinical research and practice.
40. Kaufman J, Hill S, Ryan R, Lewin S, Bosch-Capblanch X, Cliff J, et al. Developing an outcomes taxonomy and preliminary core outcomes set for evaluating communication-related interventions for childhood vaccination (the COMMVAC2 study).
41. Khan K, Alfirevic Z, Saade GR, Mol BW, van't Hooft J. Defining core outcomes for studies on prevention of preterm birth in high risk women: COPOP project.
42. Knight S, Friend P, Blazeby J, McNair AGK, Avery K, Caskey F. Developing core outcome sets for trials of immunosuppression in kidney transplant recipients.
43. Lam T, N'Dow J, MacLennan S, Ramsay C, Campbell M, Entwistle V. Development of core outcomes for surgical management of localised prostate cancer to support decision-making by patients, clinicians and policy makers (Prostate Cancer Core Outcomes Project).
44. Marson T, Jacoby A, Hughes D, Kierans C, Cooper M, Williamson P, et al. Defining patient preferences and priorities for treatment options and outcomes in epilepsy.
45. McConachie H, Williams K, Le Couteur A, Charman T. MeASURe: Measurement in autism spectrum disorder under review.
46. Meher S, Alfirevic Z, Williamson P, Kirkham JJ. Core Outcome Sets for Prevention and Treatment of Postpartum Haemorrhage.

47. Myles P, Moonesinghe R, Boney O. Core Outcome Measures in Perioperative and Anaesthetic Care (COMPAC).
48. Nixon J. Outcomes for Pressure Ulcer Trials (OUTPUT).
49. Perez R, Moseley L, Harden N, Brunner F. A multi-centre international collaboration for the development and implementation of a core data set of outcome measures for Complex Regional Pain Syndrome clinical trials.
50. Rees J, Blazeby J. Development of core outcome sets (COS) for liver surgery for metastatic disease to use in clinical trials and national audit. - LIVCoS.
51. Rees JRE, Coolsen MME, Brookes ST, Avery K, Finch-Jones MD, Jong C, et al. Development of a core outcome set to assess the benefits and adverse outcomes after pancreatic surgery in clinical trials.
52. Reilly S, Wang Y, Morbey H, Leroi I, Williamson P, Keady J, et al. The development of a dementia core outcome set for dementia care in the community
53. Riley P, Glenny A, Worthington H, Walsh T. Core outcome measures and selective outcome reporting in randomised controlled trials (RCTs) of the management of oral mucositis in cancer patients.
54. Ringrow S, Blackwood B, McAuley D, Clarke M, Rose L. Standardizing reporting of core outcome measures in ventilation studies.
55. Schwendicke F, Innes N, Lamont T. Outcomes in Trials for Management of Caries Lesions (OuTMaC).
56. Semple MG, Sinha IP. Identifying common outcome measures for epidemic and pandemic studies of severe acute respiratory infection.
57. Shokeen D, Samuelson E, Schaeffer M, Alam M. Core Outcome Set for Post-Inflammatory Hyperpigmentation (PIH).
58. Smith P, Coomarasamy A, Clark J, Ismail K, Khan K. Core outcome measures for surgical management of miscarriage.
59. Sousa Dos Santos F, Thangaratinam S, Hogg M. Development of a Core Outcome Set for trials on Induction of Labour.
60. Sun Y, Yu C, He L, Fan J. Core Outcome Sets of integrity of modern and Traditional Chinese Medicine on treatment of chronic Hepatitis B.
61. T J, Tudur Smith C, Waters A. Head and neck cancer: defining core outcome sets for clinical trials
62. Tang J, Samuelson E, Schaeffer M, Alam M. Core Outcome Set for Melasma.
63. Thangaratinam S, Khan K, Pirie A, Al Watter BH, McCorrey D, Bagary M, et al. Defining core outcomes for clinical trials in pregnant women with epilepsy (E-core): A Delphi survey.
64. Thiboutot D, Tan J, Layton A. Development of Clinical Trials Outcome Instruments for Acne Vulgaris.

65. Vasic J, Samuelson E, Goldberg L, Alam M. Core Outcome Set for Actinic Keratosis.
66. Vasic J, Samuelson E, Schaeffer M, Alam M. Core Outcome Set for Treatment of Leg Veins.
67. Wallace S, Worrall L, Rose T, Le Dorze G. Improving Research Outcome Measurement in Aphasia (ROMA): Development of a Core Outcome Set.
68. Whitehead L, Perkins G, Haywood K, Finn J, Jacobs I, Brett S, et al. the development of a core outcome set for cardiac arrest clinical trials.
69. Zajicek J, Hobart J, Wright D, Wilcock G, Ritchie C, Counsell C, et al. Clinical Trials Methods in Neurodegenerative Diseases.
70. Zha A, Samuelson E, Schaeffer M, Alam M. Core Outcome Set for Scar.
71. Zhang J, Xing D, Shang H. Developing a Core Outcome Set for Traditional Chinese Medicine for Stable Angina Pectoris.
72. Zhang Y, Du L, Fan H. Core outcome sets for tuberculosis.
73. Zoet DA, van Rijn BB, Koster MPH, Franx A, Maas AHEM, Groot CJM. Primary endpoints in cohort studies evaluating cardiovascular disease risk after reproductive disorders.

Appendix 2 – S2-Planned and ongoing studies using qualitative methods

Author	Health area	Proposed sampling	Proposed data collection methods	Proposed analytical approach
Duffy (protocol available)	Pre-eclampsia	Not stated	Systematic review Interviews Delphi	Thematic content analysis
Kaiser (protocol available)	Chronic pain	Not stated	Delphi process Interview Systematic review	Not stated
Keeley (protocol available)	Schizophrenia & Bipolar	Purposive	Focus groups Interviews Delphi Consensus meeting Literature review Stakeholder discussion Survey	Thematic iterative constant comparison, “grounded in the data”, Dual coding
Maclennan *(Lam)* (protocol available)	Prostate cancer	Purposive	Systematic review Interviews Focus groups Delphi Consensus meeting	Thematic
Waters (protocol available)	Oropharyngeal Cancer	Maximum diversity sampling	Systematic review Interviews Delphi Consensus meeting	Constant comparative, Dual coding
Alam	Facial aging	Not stated	Consensus conference Consensus meeting Delphi process Interview Systematic review	Not stated
Azuara-Blanco	Diabetic retinopathy	Not stated	Systematic review Delphi Interviews Focus groups	Not stated

Author	Health area	Proposed sampling	Proposed data collection methods	Proposed analytical approach
			Survey	
Azuara-Blanco	Age-related macular degeneration	Not stated	Systematic review Delphi Interviews Focus groups Survey	Not stated
Blazeby	Colorectal cancer	Not stated	Systematic review Interviews Delphi Consensus meeting	Not stated
Cartee	Skin cancer excision	Not stated	Consensus conference Delphi process Focus group(s) Interview Nominal group technique (NGT) Systematic review	Not stated
Chazapis	Anaesthesia	Not stated	Systematic review Survey Interviews Delphi	Not stated
Clark	Acne scarring	Not stated	Consensus conference Delphi process Focus group(s) Interview Nominal group technique (NGT) Systematic review	Not stated
Colavincenzo	Hair loss, non-scarring alopecia	Not stated	Consensus conference Delphi process Focus group(s) Interview Nominal group technique (NGT) Systematic review	Not stated
Costa	Lower limb fractures	Not stated	Systematic review Interviews Consensus meeting	Not stated
Coulman	Obesity	Not stated	Systematic review Interviews	Not stated

Author	Health area	Proposed sampling	Proposed data collection methods	Proposed analytical approach
			Delphi Consensus meeting	
Davidson	Liver	Not stated	Systematic review Interviews Survey Consensus meeting	Not stated
Denniston	Uveitis	Not stated	Focus groups Interviews Systematic review Delphi Consensus meeting	Not stated
Duffy	Endometriosis	Not stated	Systematic review Focus groups Delphi	Not stated
Duncan-Millar	Upper limb rehabilitation after stroke	Not stated	Systematic review Focus groups Interviews Delphi Survey	Not stated
Fabricius	Prostate cancer	Not stated	Systematic review Interviews Consensus meeting Delphi Consensus meeting	Not stated
Forster	Rehabilitation (older people)	Not stated	Literature review Interviews Focus groups Delphi	Grounded theory with constant comparison, Q-methodology
Goncalves	Dementia	Not stated	Clinical experts Consumers Consumers Families Patient/support group representatives Researchers	Not stated
Iyengar	Rosacea	Not stated	Consensus conference Delphi process Focus group(s) Interview	Not stated

Author	Health area	Proposed sampling	Proposed data collection methods	Proposed analytical approach
			Nominal group technique (NGT) Systematic review	
Kaufman	Childhood vaccination	Not stated	Systematic review Interviews Delphi	Not stated
Knight	Transplant surgery	Not stated	Delphi process Interview Systematic review	Not stated
Marson	Epilepsy	Not stated	Interviews Focus groups Discrete choice experiments Survey	Thematic
Myles	Anaesthesia	Not stated	Systematic review Surveys Interviews Delphi	Not stated
Reilly	Dementia	Not stated	Literature review Focus group Delphi Systematic review Stated preference survey	Not stated
Shoken	Post Inflammatory Hyperpigmentation	Not stated	Consensus conference Delphi process Focus group(s) Interview Nominal group technique (NGT) Systematic review	Not stated
Smith	Miscarriage	Not stated	Systematic review Interviews Focus groups Delphi Consensus meeting	Not stated
Tang	Melasma	Not stated	Consensus conference Delphi process Focus groups Interview	Not stated

Author	Health area	Proposed sampling	Proposed data collection methods	Proposed analytical approach
			Nominal group technique (NGT)	
Vasic	Leg veins	Not stated	Consensus conference Delphi process Focus group(s) Interview Nominal group technique (NGT) Systematic review	Not stated
Vasic	Actinic keratosis	Not stated	Consensus conference Delphi process Focus group(s) Interview Nominal group technique (NGT) Systematic review	Not stated
Whitehead	Cardiac arrest	Not stated	Systematic review Interviews Focus groups Delphi Consensus meeting	Not stated
Zajicek	Neurodegenerative diseases	Not stated	Systematic review Focus groups Interviews Survey	Not stated
Zha	Scar	Not stated	Consensus conference Focus group(s) Interview Nominal group technique (NGT) Systematic review	Not stated
Zoet	Cardiovascular disease	Not stated	Systematic review Focus group Delphi	Not stated

Appendix 3 – S3-Unpublished work

1) Jones JE. Core outcome set development: Understanding how qualitative research approaches can help to accommodate outcomes that are important to patients: University of Birmingham; Ongoing PhD project.

Appendix 4 – S4-PRISMA statement

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	6

Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6-7
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	6-7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	N/A
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	7

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	9-11 14-15

Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	19
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	16-19
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	20
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	19-24
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	Provided

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: **www.prisma-statement.org**.

Appendix 5 – Example search strategy

#4	72	#3 AND #2 AND #1 *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2000-2016*
#3	224,849	**TOPIC:** (“qualitative method*”) OR **TOPIC:** (“qualitative analysis”) OR **TOPIC:** (qualitative)OR **TOPIC:** (“computer based qualitative data collection”) OR **TOPIC:** (“online research”) *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2000-2016*
#2	31,304	**TOPIC:** (“face-to-face focus group*”) OR **TOPIC:** (“traditional focus group*”) OR **TOPIC:** (“focus group*”) *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2000-2016*
#1	83,709	**TOPIC:** (“online focus group*”) OR **TOPIC:** (asynchronous) OR **TOPIC:** (synchronous) *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2000-2016*

Appendix 6 – Example data extraction form

Papers comparing qualitative data collection methods

Data extraction form

Reference
Aims
Context
Data collection methods
Recruitment strategy/strategies
Reporting of the participant characteristics in all datasets
Analytical approach to comparing datasets
Comparison of the depth of data from each dataset
Comparisons of the interaction between participants in each dataset
Any reported use of resources required to use face-to-face and online datasets
Authors reflections on the findings

Comments

Appendix 7 – Participant contact details form

Contact details form
(Version 1; Date: 18/05/2016)

Title of study: What outcomes matter to adult burns patients that have experienced scar management therapy? (The OSCAR study)

Doctoral research: Janet Jones

First name:
……

Surname:
……

Date of birth:
……

Address:
……

……

……

……

Postcode:
……

Home phone number:
……

Mobile number:
……

Email address:
……

Please indicate your preferred method of contact:

Post ☐ Home phone ☐ Mobile ☐ Email ☐

By completing and signing this form you are agreeing to be contacted by a member of the research team based at the University of Birmingham. They will give you further information about the discussion groups that are being conducted with patients as part of the above research study.

Signature:……..

Date:……

Appendix 8 – Face-to-face Participant information leaflet

Participant Information Leaflet

(Face-to-face focus groups)
Version: 2, Date: 22/08/2016

Title of study: What outcomes matter to adult burns patients that have experienced scar management therapy?
(The OSCAR study)

Doctoral Researcher: Janet Jones

Part 1

You are being invited to take part in our research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is unclear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Following a burns injury many patients are given pressure garments to wear. It is recommended that they are worn for 23 hours a day for approximately 12-18 months. Pressure garments are intended to help prevent or reduce scarring. Patients may also use creaming and massage on a regular basis.
This study would like to better understand the outcomes that are important to you and others like you following scar management therapy, such as pressure garments.

Why have I been invited to take part?

You have been asked to take part because you have received or are still either receiving pressure garment therapy or scar management therapies such as massage and creaming following a burn injury. We are asking if you would be prepared to take part in a small discussion group (called a focus group) with about 6-8 other people who have also received scar management therapy.

Do I have to take part

No. taking part is totally voluntary. If you do not want to take part, you do not have to and you do not have to give a reason. If you decide to take part but later change your mind, you can withdraw from the study at any time and without giving a reason. Your medical care will not be affected if you do not take part.

What will I have to do if I take part?

We will invite you to take part in a group discussion (focus group) with other patients led by a researcher, about what outcomes you hope to achieve following scar management therapy, we will discuss:

- What you hope/hoped to get from the therapy
- How you feel about the therapy.
- If you think that the therapy has helped to manage the scarring
- How it has affected your life (home, work and social)

With your permission the discussion will be audio-taped and will be held at the hospital or another convenient location and should not last more than two hours.

What are the possible benefits of taking part?

You will meet other people and share experiences and ideas. This research may not directly benefit you, but what you tell us may help us to improve future treatments for burn patients.

What are the possible disadvantages and risks of taking part?

The study does not involve any treatments or tests. So there is no physical risk involved. Some people may find it upsetting to talk about their burn injury with others. If this happens the moderator will stop the discussion and check that participants are okay and happy to continue. If you remain upset you may withdraw from the research. The facilitators will have contact details of local burns support services or if necessary more immediate support will be sought, as appropriate (contacting your GP or out of hours support service).

Will my taking part in the study be kept confidential?

Yes, we will follow ethical and legal practices and all information about you will be handled in confidence. The details are included in part 2.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

You may withdraw from the study at any point. If you wish to withdraw after the focus group discussion we will be unable to remove your contributions to the anonymised focus group transcript.

What if there is a problem?

Please feel free to ask any further questions before deciding to take part in the study, or at any time during the study.

If you have concerns about any aspects of this study, you should ask to speak to the researcher:

Janet Jones, Tel no: 0121 414 8901
Email: jej370@bham.ac.uk

Who will do her best to answer your questions. If the issue is still not resolved please contact the research supervisor:

Dr Jonathan Mathers, Tel no: 0121 414 6024,
Email: j.m.mathers@bham.ac.uk

The normal National Health Service complaints mechanisms will still be available to you (if appropriate).
England: http://www.nhs.uk/Service-Search/Patient-advice-and-liaison-services-(PALS)/LocationSearch/363

Wales: 01639 683490 or see: http://www.wales.nhs.uk/sitesplus/902/home

Will my taking part be kept confidential?

Yes. All information that is collected about you during the course of the research will be kept strictly confidential. Procedures for handling and storing your information will be compliant with the Data Protection Act 1998.

The information that will be collected will include personal information such as your name, address and contact details. This will allow us to keep in touch with you during your participation in the research.

If you join the study, some parts of the data may be looked at by authorised people from the regulatory authorities to check that the study is being carried out correctly. All of the people who are authorised to see the study data will have a duty of confidentiality to you as a research participant.

What will happen to the audio -recordings?

The audio-recording of the focus group will be used to produce a typed record of the discussion (called a transcript). All details which could identify participants within the transcript will be deleted. We will analyse the transcript as part of our research.

Anonymised research data will be kept securely for 10 years after the end of the study.

What will happen to the results of the research study?

We intend to publish the results of the study in reputable scientific journals and present the results at conferences. You will not be identified in any report/publication. A summary of the research findings will be available for all participants who tell us they would like to receive one.

Who is organising and funding the research?

The University of Birmingham is sponsoring the research and the College of Medical and Dental Sciences at the University of Birmingham is funding the research.

Who has reviewed the study?

To protect your interests all research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed and given a favourable opinion by the Coventry and Warwickshire Research Ethics Committee, Ref number: 16/WM/0307.

Research team contact details

Researcher:

Janet Jones
Doctoral Researcher
Institute of Applied Health Research
College of Medical and Dental Sciences
University of Birmingham
Edgbaston
Birmingham
B15 2TT

Tel No: 0121 414 8901,

Email: jej370@bham.ac.uk

Research Supervisor:

Dr Jonathan Mathers
Institute of Applied Health Research
College of Medical and Dental Sciences
University of Birmingham
Edgbaston
Birmingham
B15 2TT

Tel No: 0121 414 6024

Email: j.m.mathers@bham.ac.uk

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UNIVERSITY OF BIRMINGHAM

Appendix 9 – Online advert

Are you receiving scar management therapy? (pressure garments, massage & creaming)

We're looking for people to take part in an online discussion group about scar management therapy following a burn injury

We would like to hear from you if:

- You are aged 16 or over
- You have worn (within the last two years) or are still wearing pressure garments to treat a burn injury and/or using massage and creaming

If you would like to participate in this discussion group study or would like to find out more about it please contact Janet Jones by Email: jej370@bham.ac.uk. Tel No: 0121 414 8901.

Appendix 10 – List of burns organisations with websites approached

Website contact list overleaf

			Contact dates										
Support group	**Web address**	**Country**	**Tel call**	**Email**	**Email**	**Date reply received**	**Y/N**	**Notes**	**Contact name**	**Contacted for additional social media push**	**Request to re tweet/advertised**		**Request to re tweet/advertised**
UK websites													
Katie Piper Foundation	https://katiepiperfoundation.org.uk/	UK		05/04/2016	13/02/2017	05/04/2016 09/03/2017	Y	Reapproached 13/2/17 as almost a year has past. No reply received. Chased up 08/03/2017 wtg reply. 09/03/2017 Placed on website, twitter, facebook and instagram	Ezinna Rospigliosi	25/05/2017	19/06/2017	25/07/2017	02/08/2017
Chelsea and Westminster NHS burn support group	http://www.chelwest.nhs.uk/services/surgery/burns-service/burns-support-groups	UK	27/02/2017	27/02/2017		06/03/2017	N	Website receives little if any traffic at all	Lisa Williams				
Dan's fund for burns	http://www.dansfundforburns.org/	UK		13/02/2017		21/02/2017	Y		Joy Huston	25/05/2017	21/06/2017	25/07/2017	02/08/2017
Changing Faces	https://www.changingfaces.org.uk/	UK		13/02/2017			N	Purpose of site emotional and social aspects of burns only	Henrietta Spalding				
British Burn Association	http://britishburnsassociation.org/	UK	27/02/2017	27/02/2017		07/03/2017	N	Healthcare professionals only	Mechema Lewis				
The Scar Free Foundation (previously known as the Healing Foundation)	http://www.scarfree.org.uk/	UK			08/03/2017	30/03/2017	N	We are a medical research Charity and cannot offer help, assistance, information or support to anyone affected by scarring and therefore would not be able to advertise your study	Amanda				
Let's Face it	http://www.lets-face-it.org.uk/	UK		13/02/2017		13/02/2017	Y	Feels as though we will not get many replies as not much traffic on website	Christine Piff	No			
Talk Health Partnership	http://www.talkhealthpartnership.com/	UK	27/02/2017	27/02/2017		27/03/2017	Y	Advertised on website 07/04/2017	Olivia Rendall Catriona Williams	Ongoing	Ongoing	Ongoing	
Bugs, Odstock burns unit facebook page and website	http://www.bugssalisbury.co.uk/	UK		21/06/2017	29/06/2017								02/08/2017
Unsuitable Websites													
Bugs Salisbury	http://www.bugssalisbury.co.uk	UK						Children only					
Fab club	http://www.fabclub.org.uk/	UK						Children only					
Burns Survivors Association	http://www.burnsurvivors.com	UK						No longer active					
Disfigurement Guidance Centre	http://timewarp.demon.co.uk	UK						No longer active					
Burns Support Group Database	http://burnsupportgroupsdatabase.com	UK						No longer active					
Burned Childrens Club	http://wwwburnedchildrensclub.org.uk	UK						Children only					
Manchester Burn Camp	http://www.manchesterburnscamps.co.uk	UK						Children only					
Children's Burns Trust	http://www.cbtrust.org.uk	UK						Children only					
Children's Burns Foundation	http://www.cbf-uk.org	UK						Children only					
Scottish Burned Children's Club	http://www.theburnsclub.org.uk	UK						Children only					

Twitter

Tweets and retweets by me
02/06/2017
21/06/2047
29/06/2017

By Anita S
02/06/2017
14/06/2017

22/06/2017 BUGS at salisbury contacted re. advertising

Appendix 11 – Online focus group participants information sheet

Participant Information Leaflet
(Online focus groups)
Version:2, Date: 22/08/2016

What outcomes matter to adult burns patients that have experienced scar management therapy?
(The OSCAR study)

Doctoral researcher: Janet Jones

Part 1

You are being invited to take part in our research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Following a burns injury many patients are given pressure garments to wear. It is recommended that they are worn for 23 hours a day for approximately 12-18 months. Pressure garments are intended to help prevent or reduce scarring. Patients may also use creaming and massage on a regular basis. This study would like to better understand the outcomes that are important to you following scar management therapy such as pressure garment.

We would like to find out

- What you hope/hoped to get from the therapy
- How you feel about the therapy.
- If you think the therapy has helped to manage the scarring
- How it has affected your life (home, work and social)

Do I have to take part?

No. taking part is totally voluntary. If you do not want to take part, you do not have to and you do not have to give a reason. If you decide to take part but later change your mind, you can withdraw from the study at any time and without giving a reason.

What will I have to do if I take part?

If you are interested in taking part in the study we will ask you to complete an online survey. This will help us to determine if you are eligible to take part. If you are eligible we will invite you to take part in a typed online group discussion (called a focus group) with other participants about scar management therapy. The discussion, which will be facilitated by a researcher, will last for approximately two weeks. We ask that you log into the discussion site as often as you like but at least once a day and spend some time to read comments and/or questions posted by others and to take part in the discussion.

What are the possible benefits of taking part?

You will interact with others who have experienced a burn injury to share experiences and ideas. This research may not directly benefit you, but what you tell us may help other burns patients in the future.

What are the possible disadvantages and risks of taking part?

The study does not involve any treatments or tests and there is no physical risk involved. Some people may find it distressing to share their experiences of burns injury with other people. Should you become upset by the discussion and feel you need support you may contact the research team on Tel no: 0121 414 8901 or email: jej370@bham.ac.uk and if you wish you may withdraw from the research. Depending on the circumstances the research team may advise you to contact an appropriate service for further support such as your GP, usual care team or an out of hours service.

Will my taking part in the study be kept confidential?

Yes, we will follow ethical and legal practices and all information about you will be handled in confidence. The details are included in part 2.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?
You may withdraw from the study at any point. If you wish to withdraw after the focus group discussion we will be unable to remove your contributions to the anonymised focus group transcript.

What if there is a problem?
Please feel free to ask any further questions before deciding to take part in the study, or at any time during the study.

If you have concerns about any aspect of this study, you should ask to speak to the researcher:

Janet Jones, Tel no: 0121 414 8901 email: jej370@bham.ac.uk

Who will do her best to answer your questions. If the issue is still not resolved please contact the research supervisor:

Dr Jonathan Mathers, Tel no: 0121 414 6024, Email: j.m.mathers@bham.ac.uk

Will my taking part be kept confidential?
Yes. All information which is collected about you during the course of the research will be kept strictly confidential. Procedures for handling and storing your information will be compliant with the Data Protection Act 1998.

The information that will be collected will include personal information such as your name and contact details. This will allow us to keep in touch with you during your participation in the research. You will be provided with a user ID and password to access the discussion site.

If you join the study, some parts of the data may be looked at by authorised people from the regulatory authorities to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant.

What will happen to any data I give?

The survey data will be anonymised and will help us to describe who took part in the research.

The discussion group content will be downloaded into a text file (a transcript) and anonymised. This transcript will then be analysed as part of our research.

Anonymised research data will be kept securely for 10 years after the study.

All other online information will be kept until the end of the study when it will be deleted.

What will happen to the results of the research study?

We intend to publish the results of the study in reputable scientific journals and to present the results at conferences. You will not be identified in any report/publication. A summary of the research findings will be available for all participants who tell us they would like to receive one.

Who is organising and funding the research?

The University of Birmingham is sponsoring the research and the College of Medical and Dental Sciences at the University of Birmingham is funding the research.

Who has reviewed the study?

To protect your interests all health related research is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed and given a favourable opinion by the Coventry and Warwickshire Research Ethics Committee, ref number: 16/WM/0307.

Research team contact details

Researcher:

Janet Jones
Institute of Applied Health Research
College of Medical and Dental Sciences
University of Birmingham
Edgbaston
Birmingham
B15 2TT

Tel No: 0121 414 8901

Email: jej370@bham.ac.uk

Research Supervisor:

Dr Jonathan Mathers
Institute of Applied Health Research
College of Medical and Dental Sciences
University of Birmingham
Edgbaston
Birmingham
B15 2TT

Tel No: 0121 414 6024

Email: j.m.mathers@bham.ac.uk

Appendix 12 – Online consent form and screening questionnaire

1. User ID

All questions on this survey require a response and participants will not be able to move to the next page until a response is selected.

1. Please insert the ID code given to you by the research team *****

2. Consent

2. Consent Thank you for expressing an interest in the above research study. Please read the participant information leaflet we sent you BEFORE completing this survey. The answers you provide will determine your eligibility to take part in a discussion group. Once you have completed and submitted the questionnaire, then the researchers will contact you to let you know if you are eligible or not. All data collected from this survey will be used and stored securely by the research team at the University of Birmingham in accordance with the Data Protection Act 1998. By completing and submitting this survey you are consenting for your data to be used to inform the study and to assess your eligibility to take part in an online discussion group. Should you be eligible to take part in an online discussion please indicate below that you are also agreeing: *****

	Yes	No
To take part in an online discussion. I understand that my participation is voluntary and that I am free to withdraw at anytime	☐	☐
For authorised individuals from the University of Birmingham and the regulatory authorities to have access to the data collected as part of this research	☐	☐
To the use of anonymous quotes in any publication of the research findings	☐	☐
For anonymised data from the discussions to be used for future research and analysis	☐	☐

If no is selected for any of the first three items the participant will be directed to a page telling them that they are disqualified from the survey and will be asked to contact the research team (contact numbers given)

3. Background Information

3. Gender *

	Male	Female	Prefer not to say
What is your gender?	☐	☐	☐

4. Ethnicity *

	White	Asian/Asian British	Mixed/multiple ethnic groups	Black/African/Caribbean/Black British	Other, please specify below
What is your ethnic group?	☐	☐	☐	☐	☐

Comments:

5. Marital status *

	Single	Married/civil partnership	Cohabiting/living together	Separated	Divorced	Widowed
What is your legal marital status?	☐	☐	☐	☐	☐	☐

4. Qualifications and Employment

6. Qualifications *

	No formal qualifications	O level, CSE, GCSE, Foundation diploma	Apprenticeship	AS or A level, Advanced GNVQ	Degree (e.g. BA/BSc)	Higher degree (e.g. Msc, PhD)	Professional qualification (e.g. nurse/teacher)	Other, please specify below
What is your highest qualification?	☐	☐	☐	☐	☐	☐	☐	☐

Comments:

7. Employment *

	Employed, please state your occupation below	Self-employed	Unemployed	Housewife/husband	Retired	Other please state below
Are you currently employed?	☐	☐	☐	☐	☐	☐

Employed, please state your occupation below	Self-employed	Unemployed	Housewife/husband	Retired	Other please state below

Comments:

5. Burn Injury

8. What date did your burn injury occur? *

DD/MM/YYYY

9. What type of burn injury did you suffer? (Please select all that apply) *

- [ ] Scald
- [ ] Flame
- [ ] Chemical
- [ ] Electrical
- [ ] Radiation
- [ ] Friction
- [ ] Contact
- [ ] Other, please specify below

Comments:

10. Percentage *

Please complete

What percentage of your body was affected by the burn? *If you don't know or are unsure please write this in the box*

11. Body area *

Please specify

Which area/s of your body was/were injured? (e.g. right hand and forearm)

12. Skin grafts *

	Yes	No
Did you need skin grafts?	☐	☐

6. Pressure garment therapy

13. Do/did you wear pressure garments? *

- [ ] Yes
- [ ] No
- [ ] Unsure

If participant selects NO they will automatically be directed to page 9.

7. Pressure garment therapy continued

14. What type/s of pressure garment do/did you wear? (please select all that apply) *

- [ ] Armband/s
- [ ] Chinstrap
- [ ] Glove
- [ ] Gauntlet
- [ ] Leggings
- [ ] Shorts
- [ ] Sock/s
- [ ] Sternal strap
- [ ] Vest/jacket
- [ ] Not Applicable
- [ ] Other (please specify):

If a participant selects Not Applicable they will be automatically directed to page 9

8. Pressure garment therapy continued

15. Wearing pressure garments *

	Hours (please specify)
On average, how long do/did you wear your pressure garment/s for each day (each 24 hour period including day and night)?	

16. In total, how long do you think you will have to/did you wear your pressure garments for? Please specify whether weeks, months or years *

9. Other treatments

17. Do/did you use other treatment/s instead of or in addition to pressure garment therapy? (Please select all that apply) *

- [ ] No
- [ ] Desensitisation
- [ ] Massage
- [ ] Silicon
- [ ] splinting
- [ ] steroid injections
- [ ] stretches
- [ ] ultrasound
- [ ] Other (please specify):

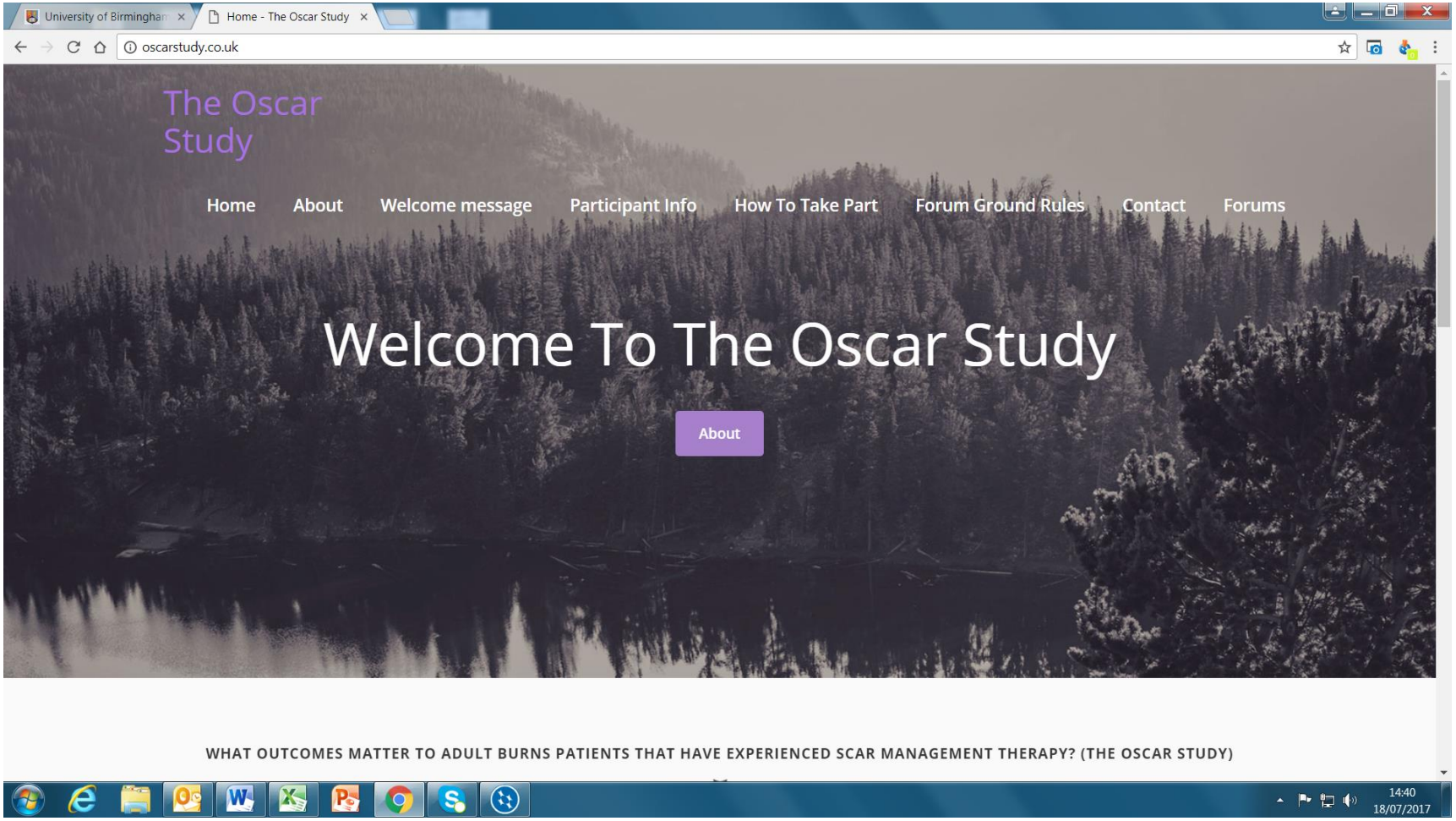
10. Return to work

18. Have/did you return to employment/education whilst still undergoing scar management therapy? *****

- [ ] Yes, I have returned to work/education
- [ ] No, but I am actively seeking employment
- [ ] No, I have not yet returned to work/education
- [ ] Not applicable

End of survey and thank you message will appear after survey is completed

Appendix 13 – Screenshot of study website



Appendix 14 – Online focus group ground rules

Online discussion groups – ground rules

Version: 1, Date 18/05/2016

What outcomes matter to adult burns patients that have experienced scar management therapy? (The OSCAR study)

Doctoral researcher: Janet Jones

Please remember you are welcome to log in as often as you wish each day but please remember that you must log in at least once per day. This will allow you to read and respond to comments left by others and any questions asked by the facilitator, to make comments of your own, and to participate in the general discussion. Please note

So that it is easy for you to identify the facilitator's contributions the daily summary, questions and any comments will be typed in capital letters.

Whilst the discussion is in progress please remember the following:

1. **Respect everyone's views**
2. **Be polite to everyone**
3. If you disagree with someone's comments please say so and explain why, **but do it nicely**
4. Please **do not** type in capital letters
5. Feel free to use emoticons to express your emotions
6. Remember there are no right or wrong answers/comments
7. Enjoy the discussion

If you have any more questions please contact me by email: jej370@bham.ac.uk or tel no: 0121 414 8901.

Appendix 15 – Online focus group welcome message

Welcome message
Version: 2, Date: 10/08/2016

What outcomes matter to adult burns patients that have experienced scar management therapy? (The OSCAR study)

Doctoral researcher: Janet Jones

Hello

Welcome to the OSCAR study and thank you for completing the online survey. We are pleased that you have agreed to take part in this research study. Your views and opinions will be extremely helpful to us.

I'd like to introduce myself. My name is Janet Jones and I am the PhD researcher who has organised this study. I am based at the University of Birmingham in Birmingham, UK.

Before you take part in the discussion group, if you haven't done so already, please familiarise yourself with the study by reading the participant information leaflet and the discussion ground rules which have been sent to you. This information will also be available on the website so you can refer to them as often as you need to.

The discussion will be open for approximately two weeks. We would like you to log in as often as you would like but at least once a day for the duration of the study. Please spend some time taking part in the discussion by reading and responding to posts and questions posed by others and asking questions yourself. Each morning I will enter the discussion group and summarise what has been discussed the day before, I may also post a question for you all to discuss.

We hope that this discussion will be constructive and informative for all involved however, should you start to become upset by the discussion please contact me using the details below. It may also be advisable to contact your GP or usual care team if you feel that you will benefit from additional support.

Please remember there are no right or wrong answers and this is not a test. We're really interested in hearing everyone's views and experiences.

I hope you find taking part in the discussion enjoyable.

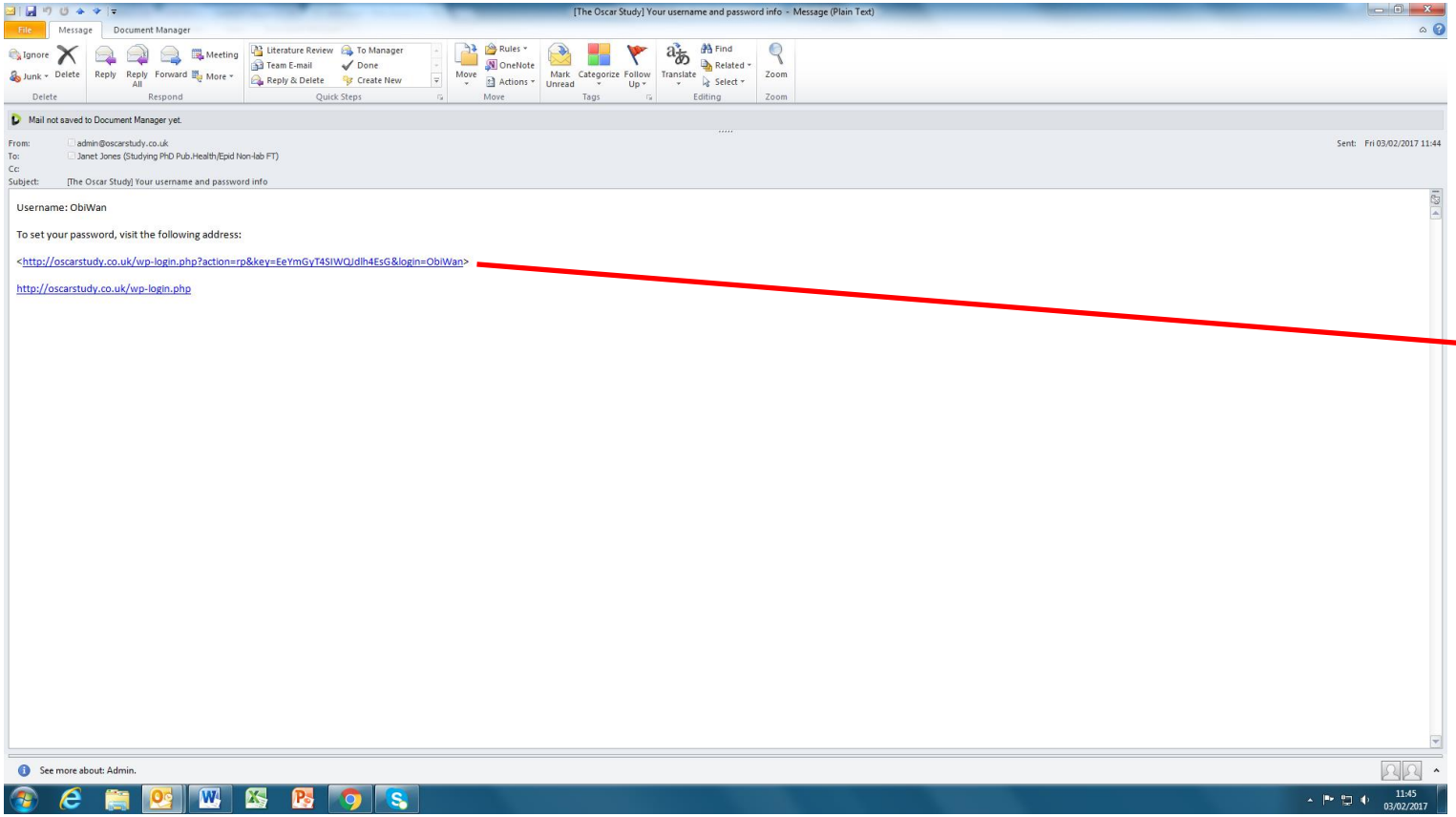
If you have any questions, please do not hesitate to contact me Tel no: 0121 414 8901, Email: jej370@bham.ac.uk

Best wishes

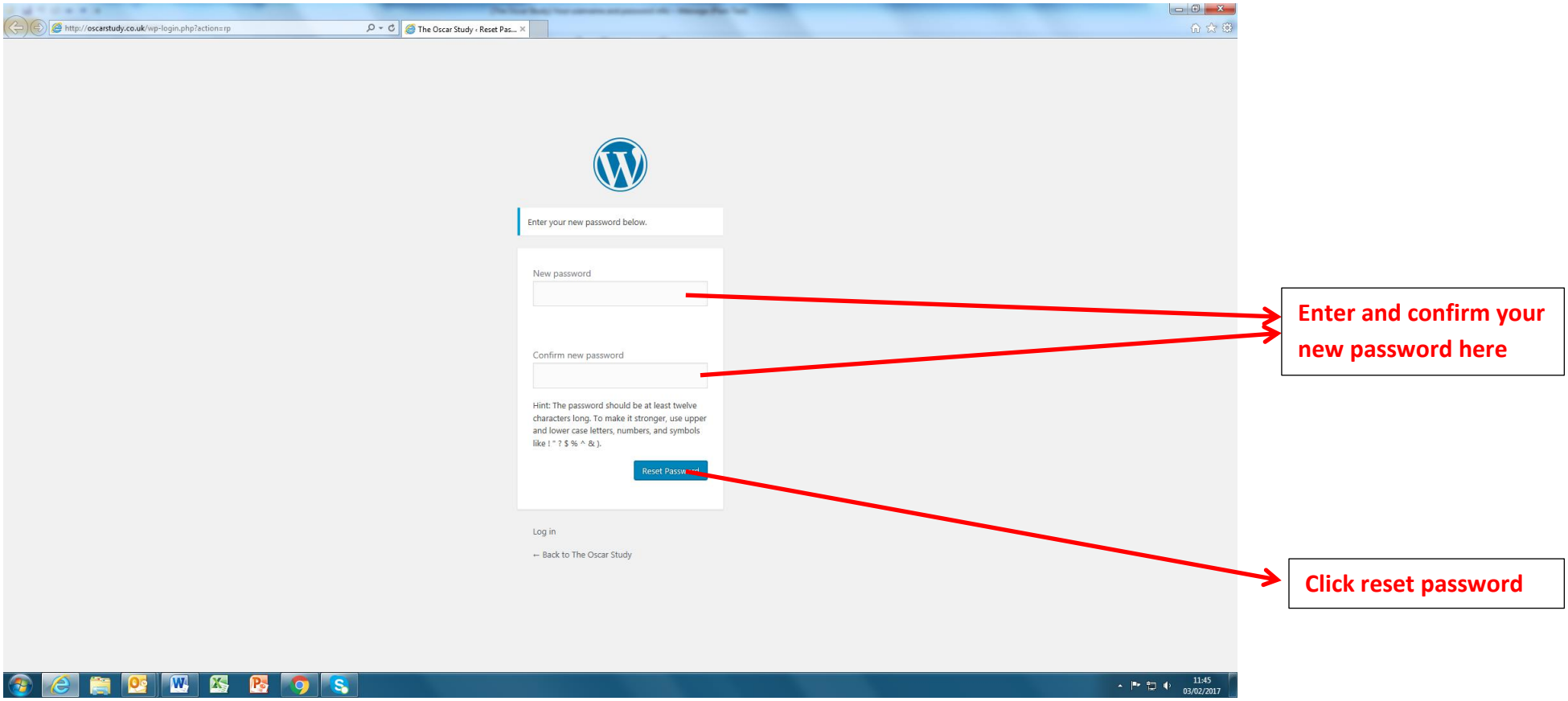
Janet

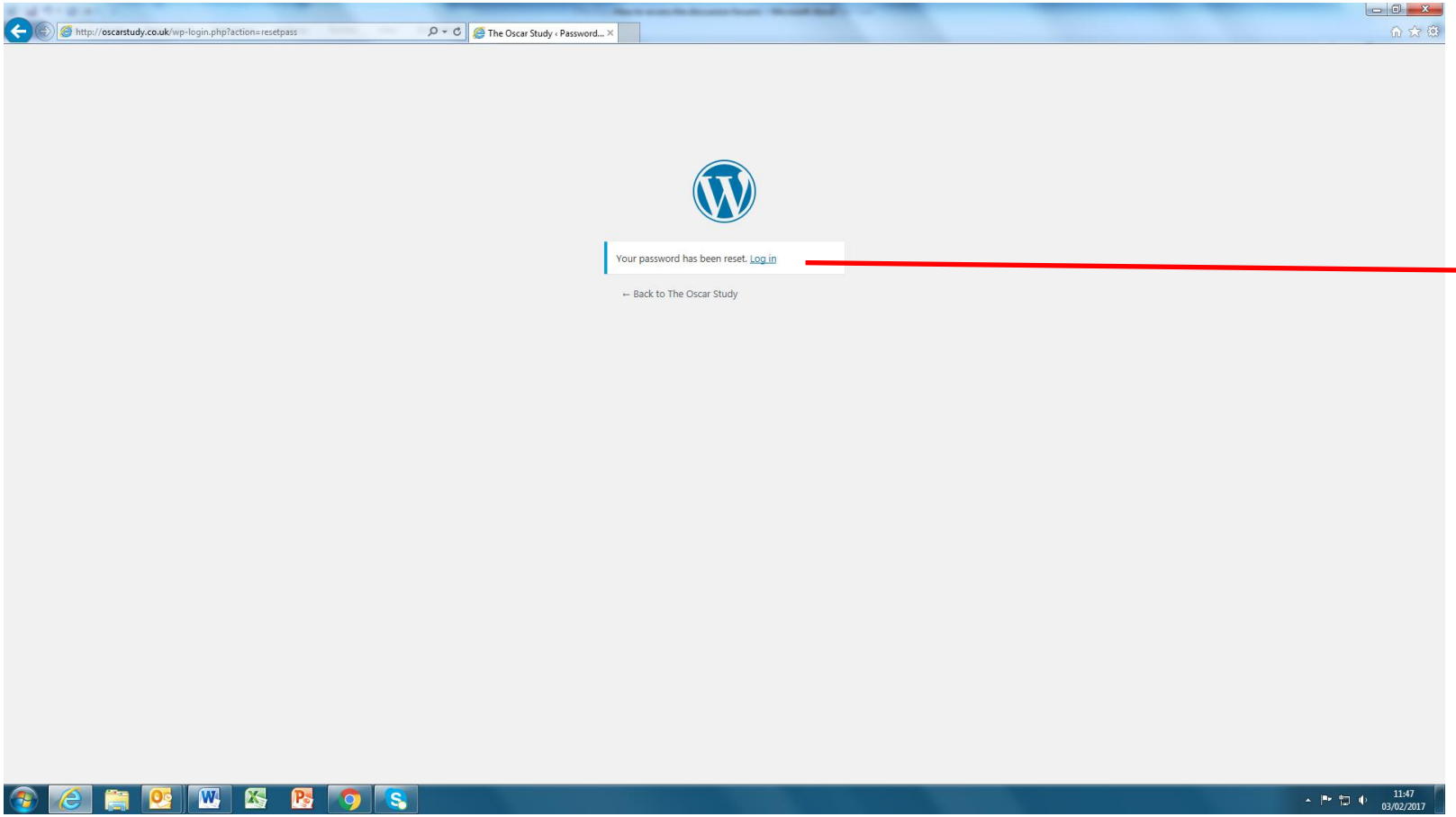
Appendix 16 – Instructions on how to access the online focus group

When you are first registered to take part in a discussion forum you will receive a welcome email like the one below:



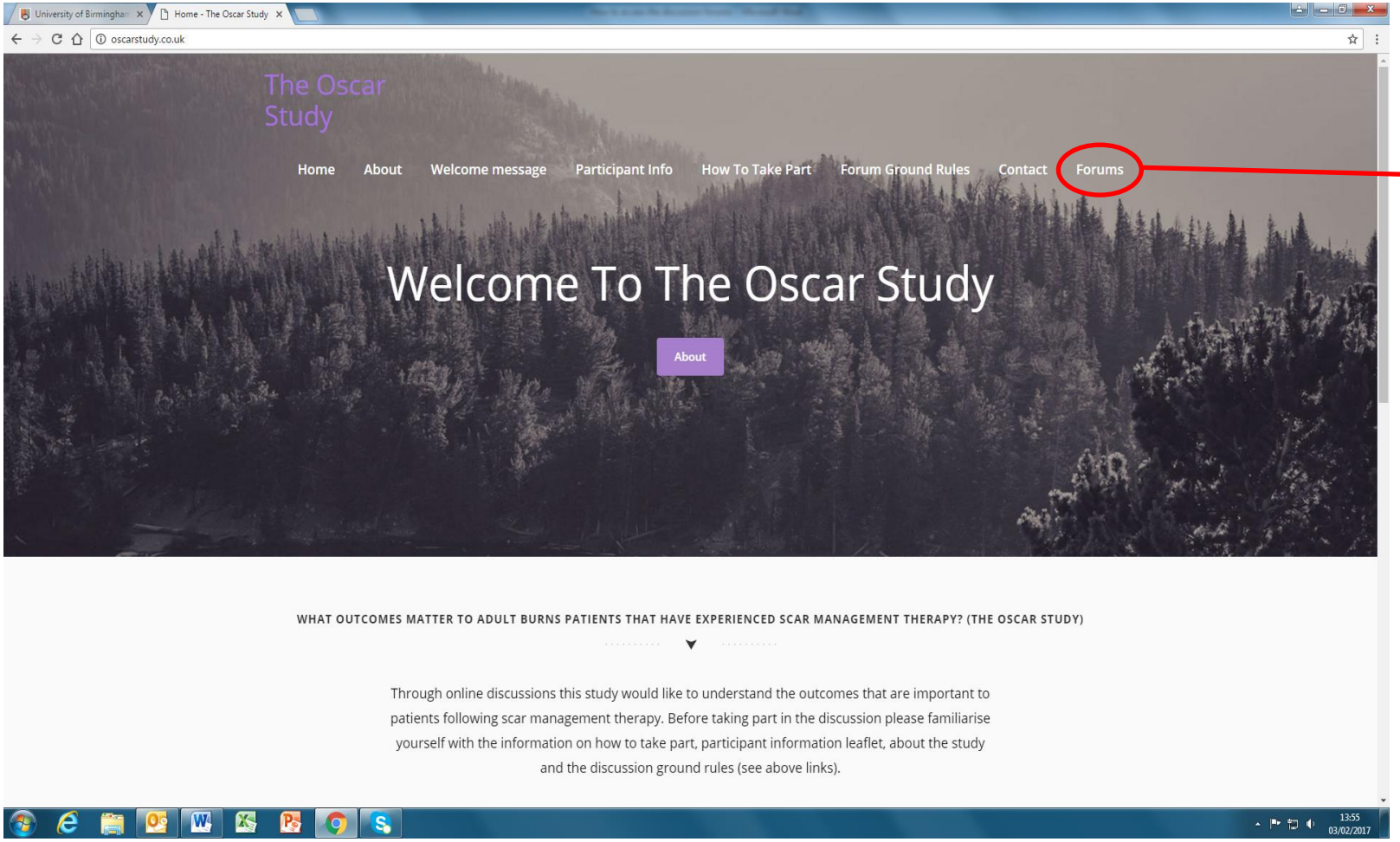
PLEASE NOTE: this email may go into your SPAM box. **Please move the message from your SPAM box to your inbox otherwise the links will not work**.



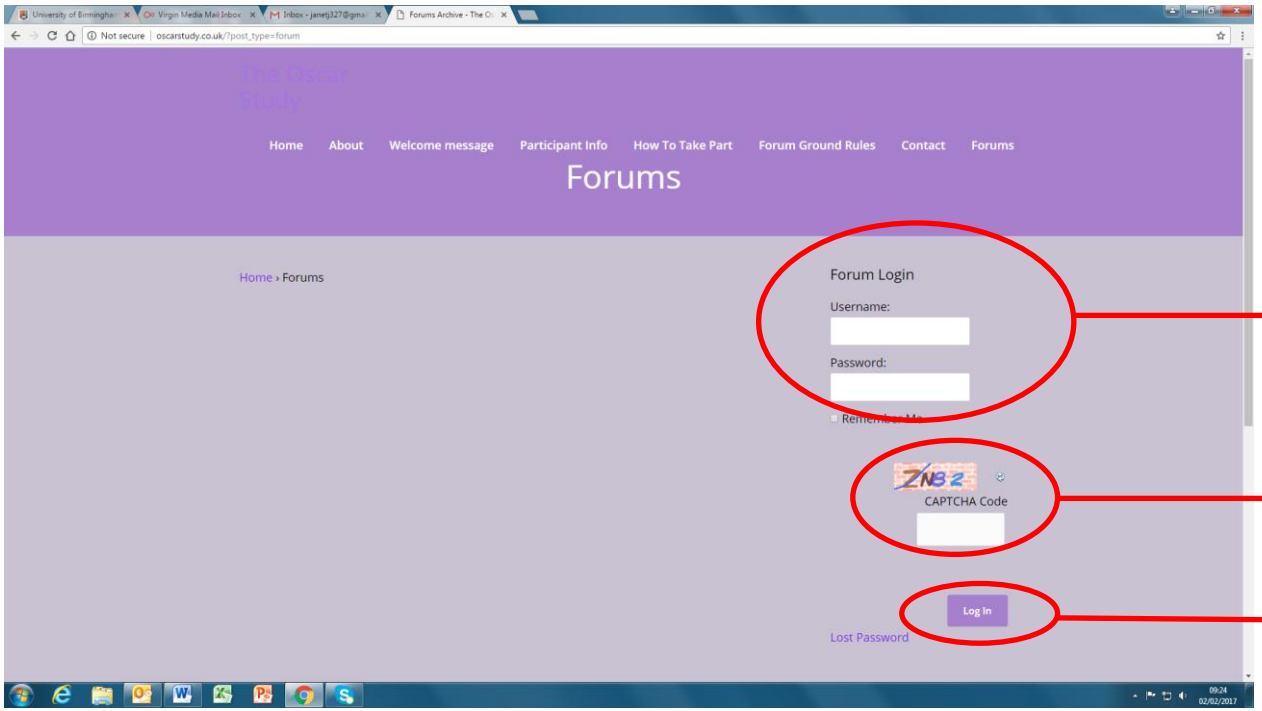


You can log into the Oscar study website from here.

For future access to the study website type **oscarstudy.co.uk** into your browser. This will bring up the home page:



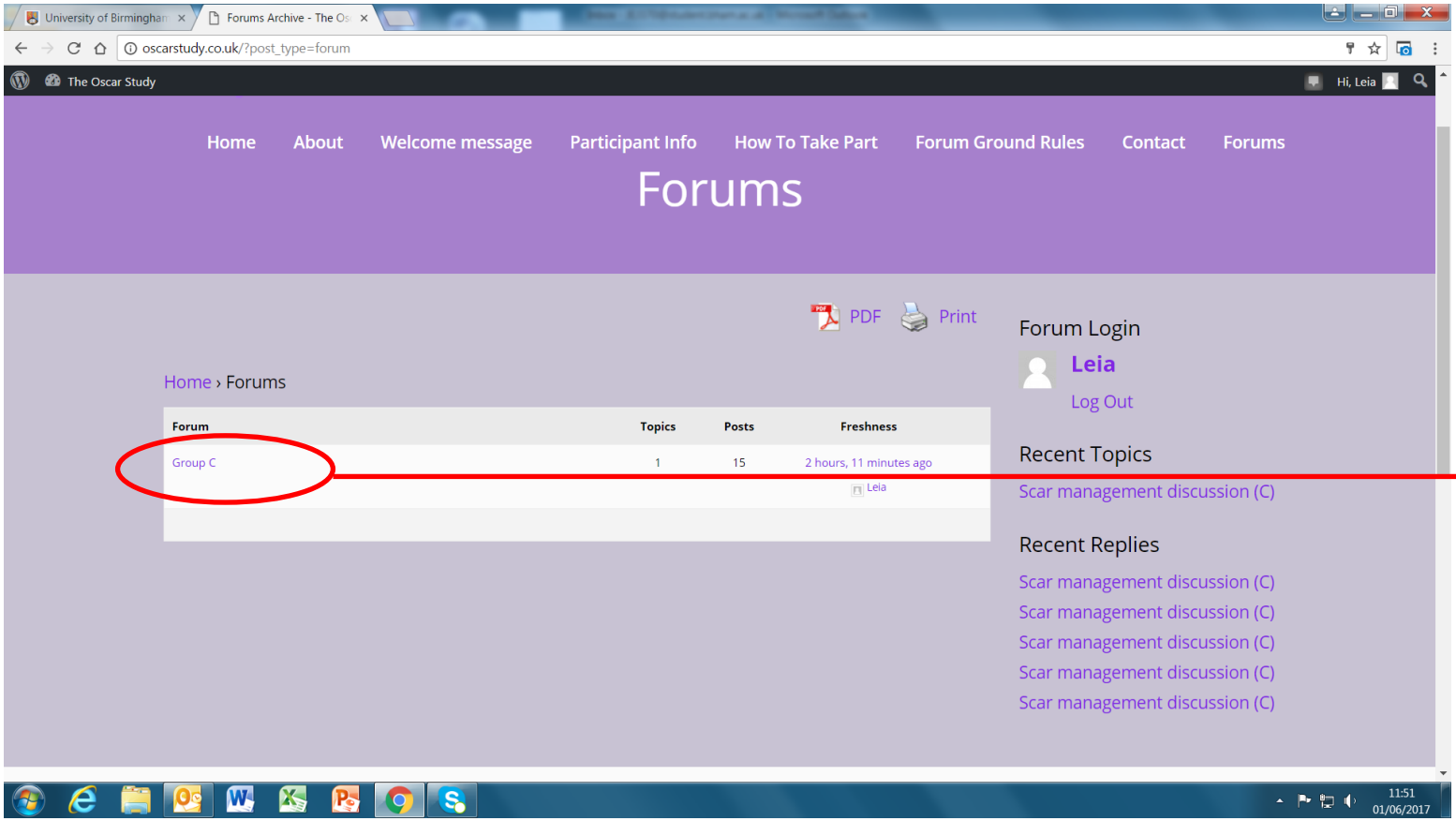
Click here to access the forum



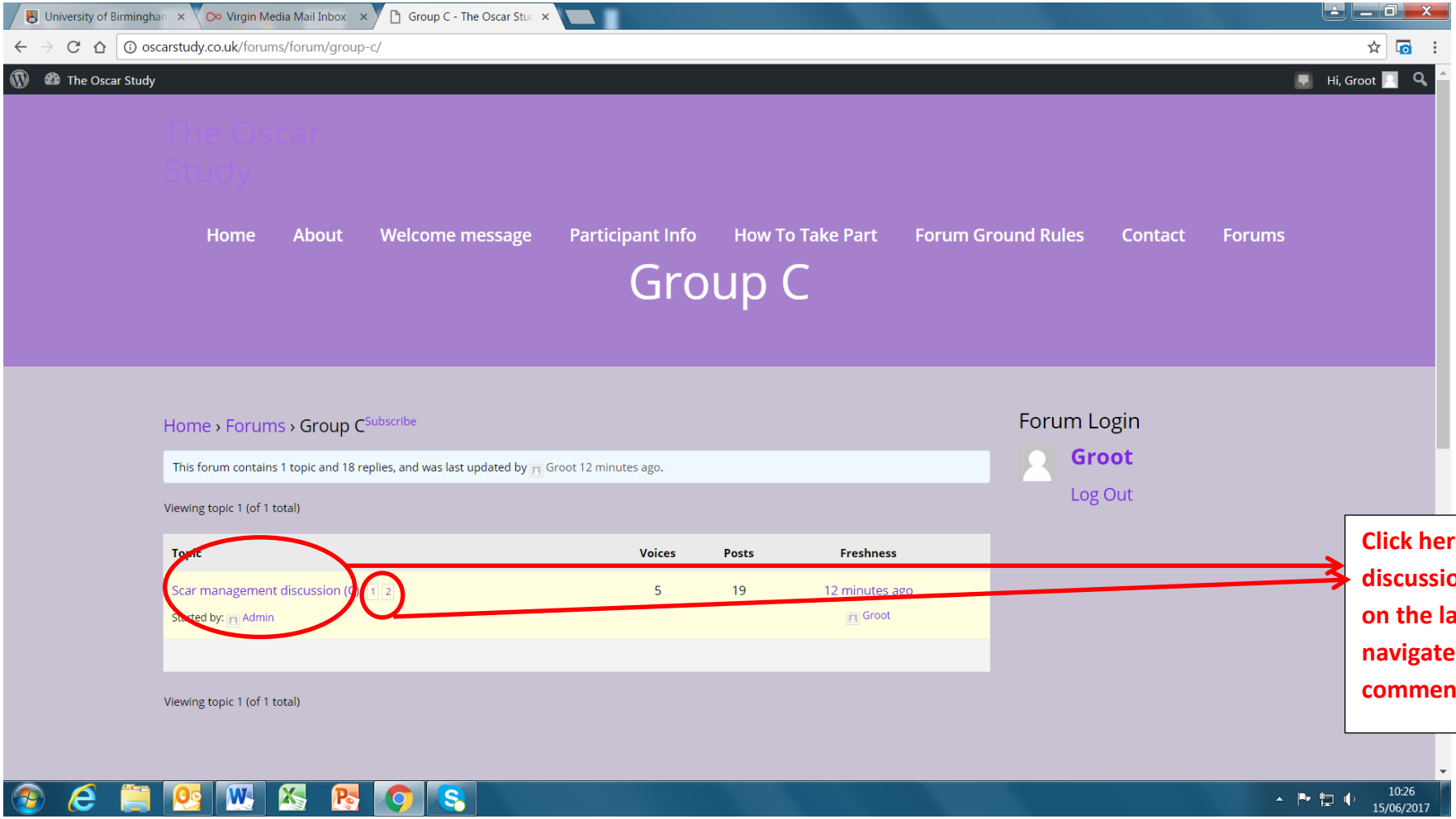
Enter your username and password here

Enter captcha code

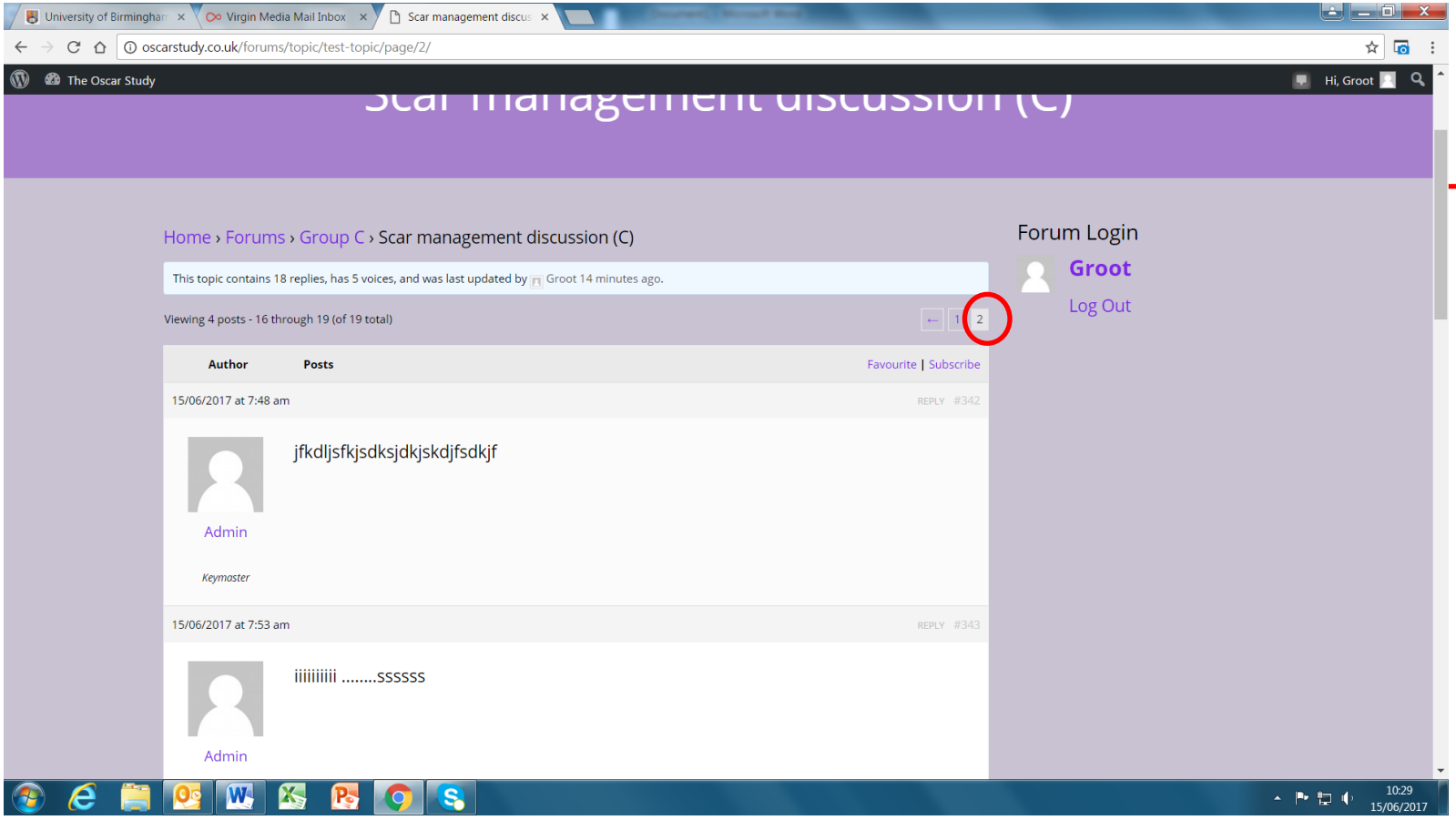
Click Log in



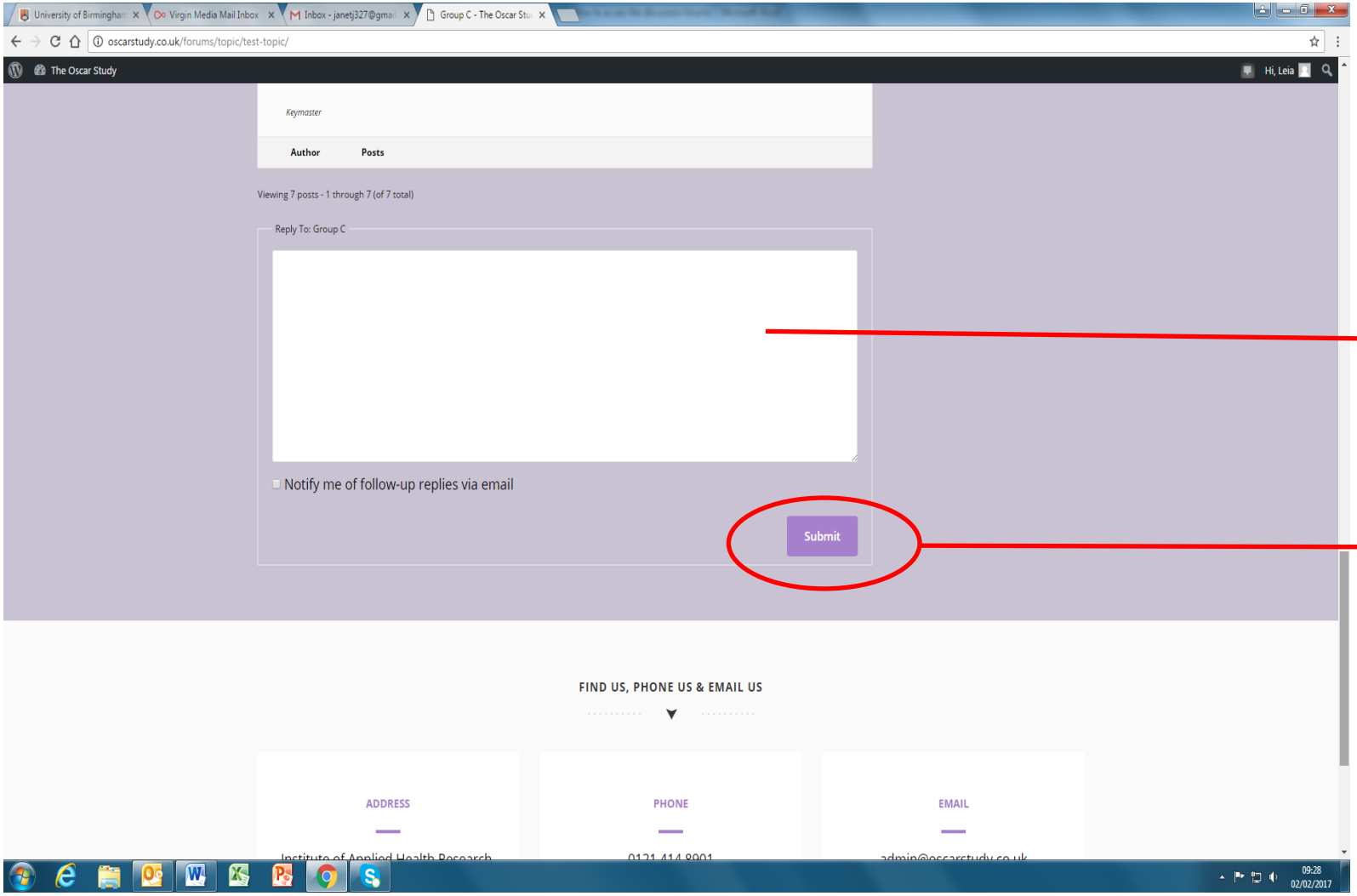
Click here to enter the forum


University of Birmingham
Virgin Media Mail Inbox
Group C - The Oscar Study
oscarstudy.co.uk/forums/forum/group-c/
The Oscar Study
Hi, Groot
The Oscar Study
Home
About
Welcome message
Participant Info
How To Take Part
Forum Ground Rules
Contact
Forums
Group C
Home › Forums › Group C Subscribe
This forum contains 1 topic and 18 replies, and was last updated by Groot 12 minutes ago.
Viewing topic 1 (of 1 total)
Topic
Voices
Posts
Freshness
Scar management discussion (1 2)
5
19
12 minutes ago
Started by: Admin
Groot
Viewing topic 1 (of 1 total)
Forum Login
Groot
Log Out
Click here to enter the discussion. By clicking on the last page you can navigate to the latest comments.
10:26
15/06/2017

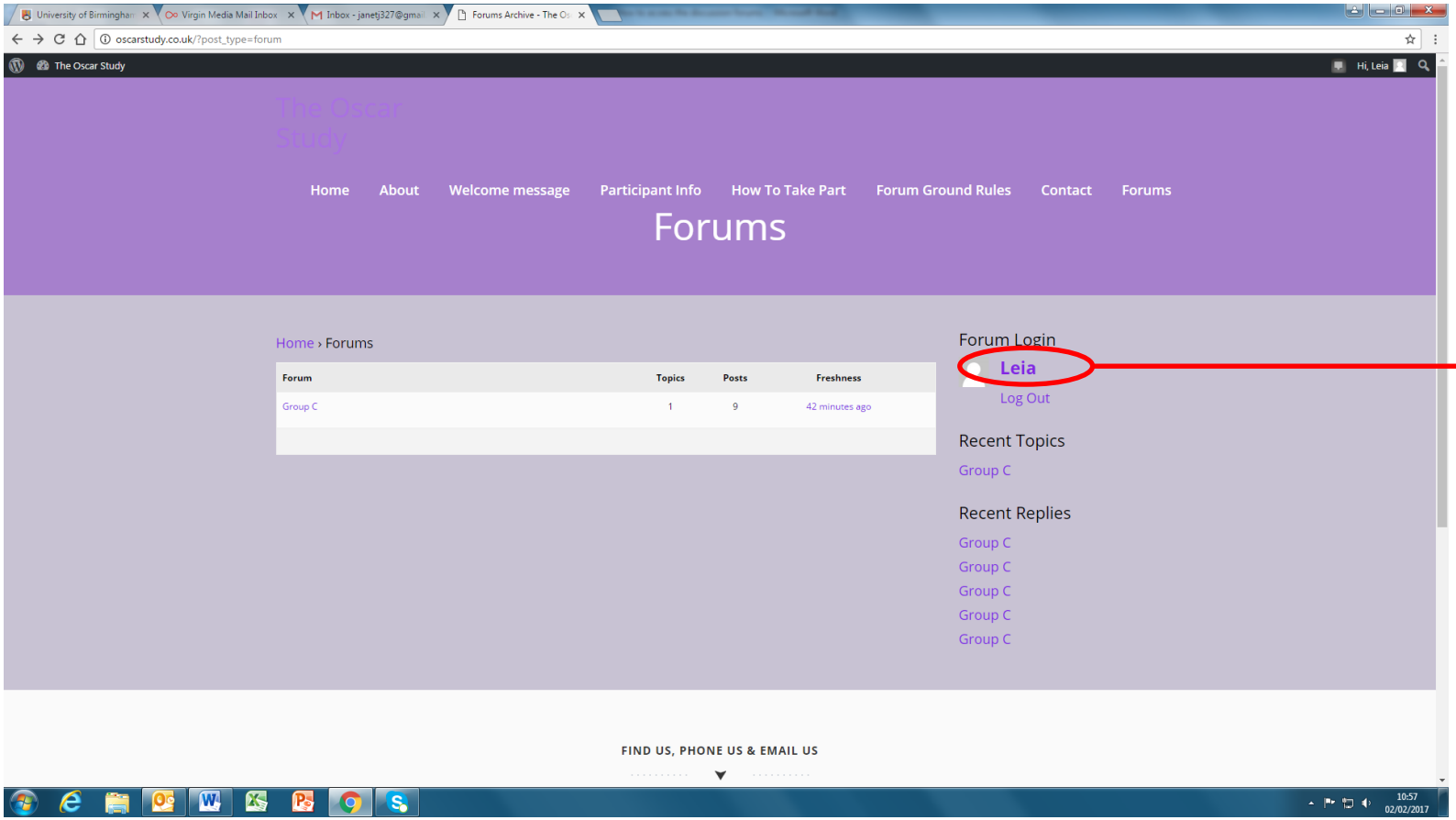
The most recent comments will be on the last page.



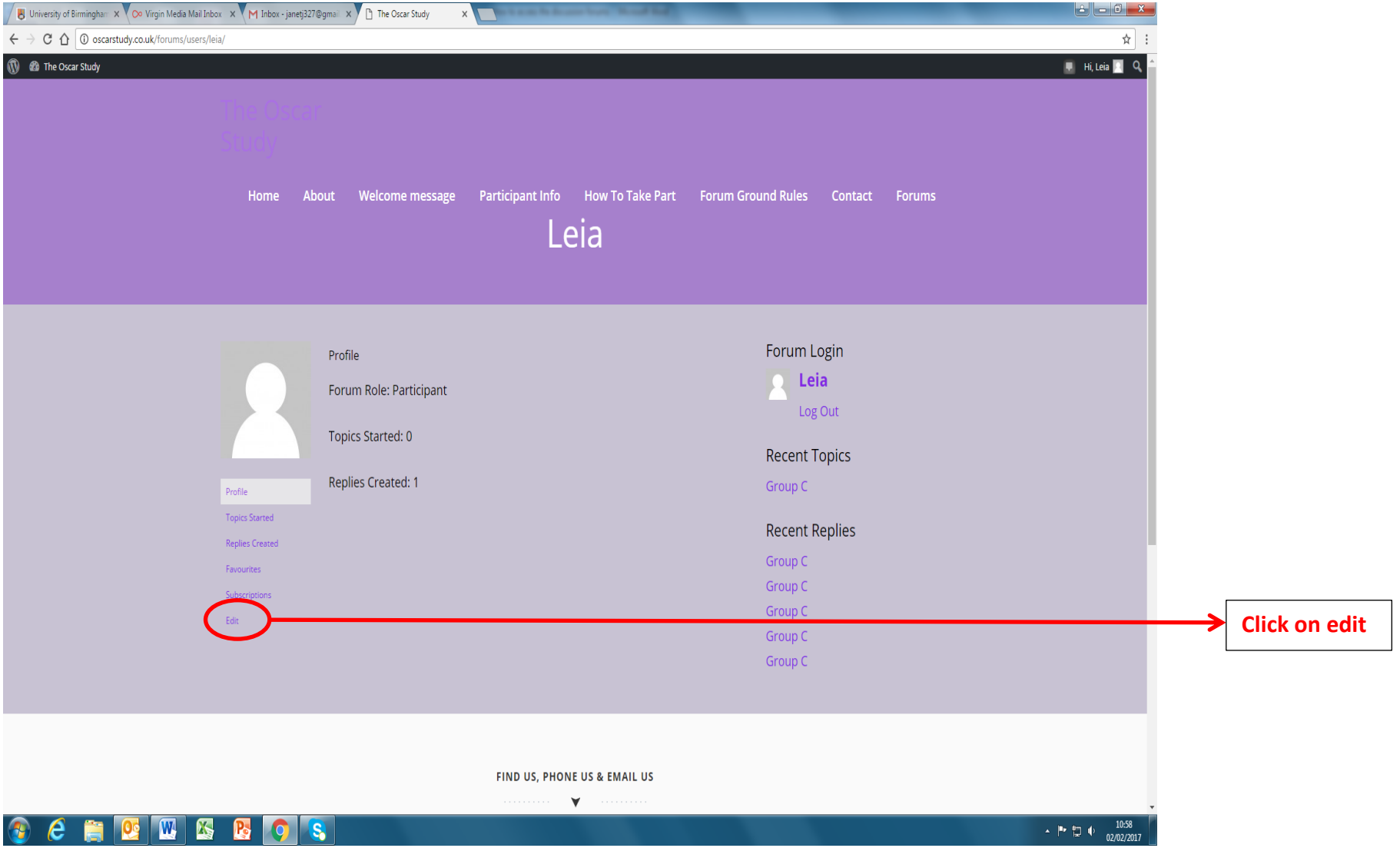
Scroll to the bottom of the page to add your comments

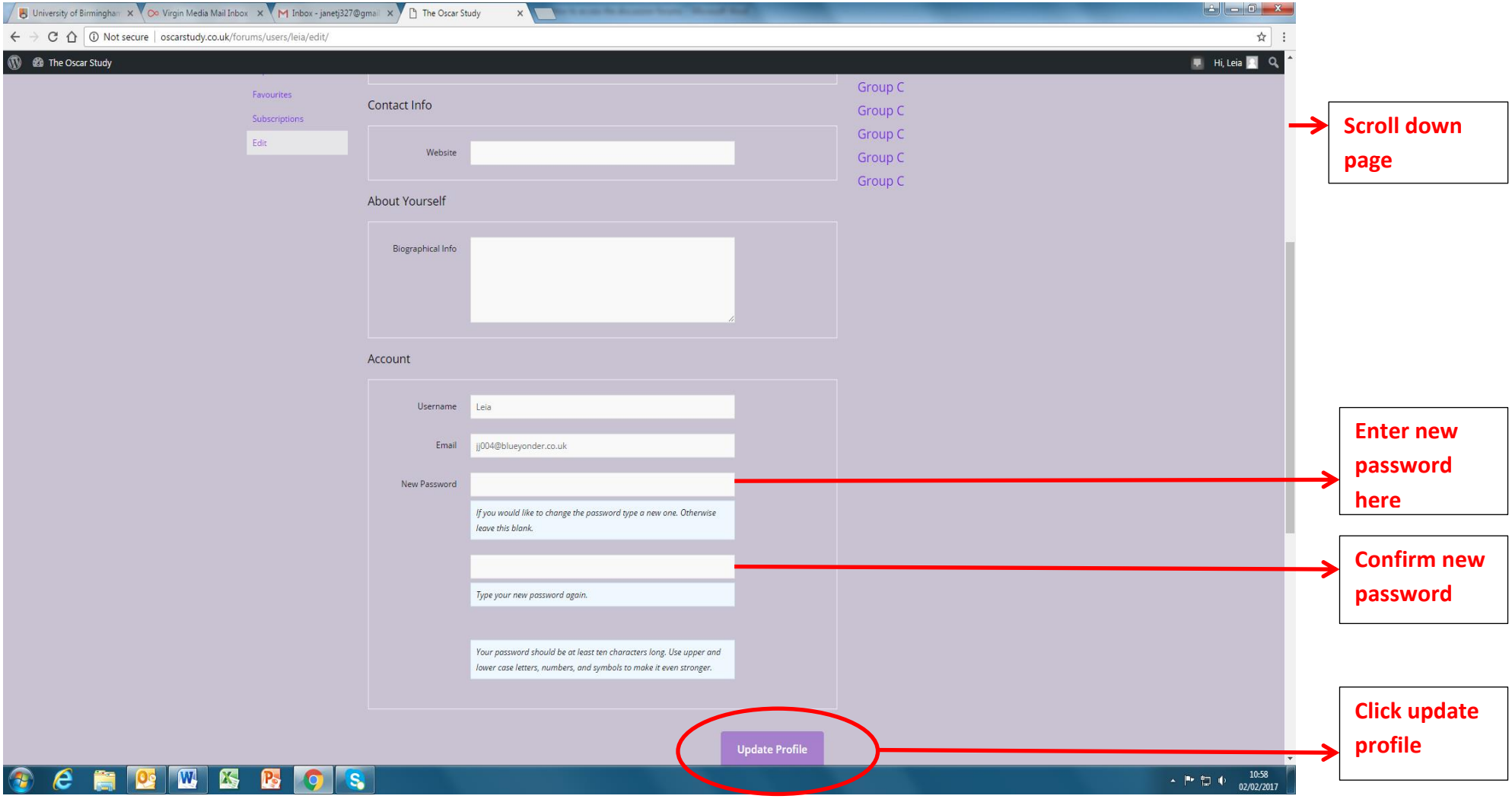

oscarstudy.co.uk/forums/topic/test-topic/
The Oscar Study
Hi, Leia
Keymaster
Author
Posts
Viewing 7 posts - 1 through 7 (of 7 total)
Reply To: Group C
Notify me of follow-up replies via email
Submit
FIND US, PHONE US & EMAIL US
ADDRESS
PHONE
EMAIL
Enter your comments here
Click submit

How to change your password



Click on your username


oscarstudy.co.uk/forums/users/leia/
The Oscar Study
Hi, Leia
The Oscar Study
Home
About
Welcome message
Participant Info
How To Take Part
Forum Ground Rules
Contact
Forums
Leia
Profile
Forum Role: Participant
Topics Started: 0
Replies Created: 1
Profile
Topics Started
Replies Created
Favourites
Subscriptions
Edit
Forum Login
Leia
Log Out
Recent Topics
Group C
Recent Replies
Group C
Group C
Group C
Group C
Group C
FIND US, PHONE US & EMAIL US
10:58
02/02/2017
Click on edit



Your password has now been changed. You should receive a confirmation email.

Appendix 17 – Face-to-face focus group consent form

Consent Form

(Face-to-face Focus group)
Version: 1, date: 18/05/2016

Title of study: What outcomes matter to adult burns patients that have experienced scar management therapy? (The OSCAR study)
Doctoral researcher: Janet Jones

		Participant: Please initial each section	Researcher: Please initial each section
1.	I confirm that I have read and understood the information leaflet version 2, dated 22/08/2016 for the above study and have had the opportunity to ask questions and have had these answered to my satisfaction		
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected		
3.	I agree to take part in the above study and consent to participate in a focus group		
4.	I agree to the focus group being audio-recorded and understand that the recordings will be kept safe at the university of Birmingham and that everything I say will be kept confidential in accordance with the Data Protection Act 1998		
5.	I give permission for authorised individuals (from the University of Birmingham, regulatory authorities or from the NHS) to have access to relevant sections of my medical notes and data collected during this research.		
6.	I agree that quotes from the focus group can be used anonymously in any publication of the research findings		
7.	I agree that the anonymised data from the focus group can be used for future research and analysis		

Name of person giving consent (Participant)	Date	Signature

Name of person taking consent (Researcher)	Date	Signature

When completed, one copy for participant, one copy for research site file

Appendix 18 – Face-to-face focus group questionnaire

Background Questionnaire
(Version: 1**, date:** 18/05/2016**)**

Title of study: What outcomes matter to adult burns patients that have experienced scar management therapy? **(The OSCAR study)**

Doctoral researcher: Janet Jones

BACKGROUND INFORMATION

1. What is your gender?

☐ Male ☐ Female ☐ Prefer not to say

2. What is your age?

_____ Years

3. What is your ethnic group?

☐ White
☐ Mixed/ multiple ethnic groups
☐ Asian/ Asian British
☐ Black/ African/ Caribbean/ Black British
☐ Other

_____
(please specify)

4. What is your legal marital status? (Please tick only one box)

☐ Single
☐ Married/Civil Partnership
☐ Cohabiting/living together
☐ Separated
☐ Divorced
☐ Widowed

QUALIFICATIONS AND EMPLOYMENT

5. What is your highest qualification? (Please tick only one box)

☐ No formal qualifications
☐ O levels/ CSEs/ GCSEs/ Foundation Diploma
☐ Apprenticeship
☐ AS or A Levels/ Advanced GNVQ

☐ Degree (e.g. BA/ BSc) ☐ Higher Degree (e.g. MSc/ PhD)
☐ Professional Qualification (e.g. nurse/ teacher)
☐ Other -
_____
(please specify)

6. Are you currently employed?
☐ Employed ☐ Self-employed ☐ Other, Please state_____

If you are employed, please state your occupation here:
_____

☐ Housewife/ husband ☐ Unemployed
☐ Retired

BURN INJURY

7. What date did your burn injury occur?
(DD/MM/YYYY)

8. What type of burn injury did you suffer?
☐ Scald ☐ Radiation
☐ Flame ☐ Friction
☐ Chemical ☐ Contact
☐ Electrical
☐ Other -
_____
(please specify)

9. What percentage of your body was affected by the burn?
_____% (please specify) ☐ Don't know/unsure

10. Which area/s of your body was/were injured? (e.g. right hand and forearm)
_____
_____ (please specify)

11. Did you need skins grafts?

☐ Yes ☐ No

PRESSURE GARMENT THERAPY

12. Do/did you wear pressure garments?

☐ **Yes** (answer all remaining questions) ☐ **No** (go to Question 16)

☐ Unsure (Please answer any of the questions below if they are relevant to you)

13. What type/s of Pressure Garment do/did you wear? (please tick all that apply)

☐ Glove
☐ Gauntlet
☐ Vest/jacket
☐ Sock/s
☐ Sternal strap
☐ Other -

☐ Leggings
☐ Shorts
☐ Armband/s
☐ Chinstrap

_____ (please specify)

14. On average, how long do/did you wear your pressure garment for each day (each 24 hour period including day and night)?

_____ hours (please specify)

15. In total, how long do you think you will have to/did you wear your pressure garment for? (add/delete as appropriate)

_____ (weeks)
_____ (months)
_____ (years)

16. Do/did you use other treatment/s instead of or in addition to pressure garment therapy? (please tick all that apply)

☐ No
☐ Splinting
☐ Silicon

☐ Massage
☐ Ultrasound
☐ Stretches

☐ Desensitisation ☐ Steroid injections

☐ Other

_____

(please specify)

17. Have/did you return to employment/education whilst still undergoing scar management treatment?

☐ Yes, I have returned to work/education

☐ No, but I am actively seeking employment

☐ No, I have not yet returned to work/education

☐ Not applicable

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE

Appendix 19 – face-to-face focus group topic guide

Focus Group Topic Guide

Version 1; Date 18/05/2016

Title of study: What outcomes matter to adult burns patients that have experienced scar management therapy? (The Oscar study)

Doctoral Researcher: Janet Jones

JJ/JM/LJ	**Equipment required** • Sticky labels for name tags • Pens and whiteboard/flipchart markers • Recorder x 2 • Spare batteries • Notepad • Ground rules • Flipchart • Post-it notes • Consent forms • Copies of P.I.L. • Questionnaires • Blutack **Set up the room** If possible arrange the furniture so that the participants are facing each other. Set up refreshments at the side of the room. Decide the best place to set up the recorder(s) (middle of the table in order to capture everyone's voice?). Test out the recorder. Put the ground rules up on the wall. Put up diagram outlining structure of the focus group. Lay out consent forms, questionnaires and P.I.L. on the desks. **Arrival of participants** Meet participants in the pre-arranged locations and take to the focus group venue (use lifts where available).

	Arrival in the room Please help yourself to a drink. We have tea, coffee, orange juice, water. I will be sitting here and Jonathan will be sitting there. Please feel free to sit anywhere else. We are expecting 6 people today. I may need to leave the room but if you have any questions Jonathan is here to help you. **Signing of consent forms:** In front of you there are two consent forms. We would like you to complete both. One copy is for you and the other for us. (Please let us know if you require any help in completing the consent form) **Completion of questionnaire** When you are ready could you please complete a questionnaire, there should be one on the desk in front of you. As you will see this will be completely confidential as there are no identifiers on it. (Please let us know if you require help in completing the questionnaire). **Collect in the completed consent forms and questionnaires** **Prior to start of Focus Group** • Housekeeping – Toilets, exits, fire alarms (we are not expecting a fire alarm test today so if the alarm sounds we will need to evacuate the building)

JJ	• If you need to use the toilets, please just get up and excuse yourself • Name badges. • If anyone needs a break from the discussion for any reason just let us know.

JJ	**Introduction** *Introduce self / co-facilitator:* Thank you for coming today. My name is Janet and I am a postgraduate researcher at the University of Birmingham. This is Jonathan (or Laura) who will introduce himself/herself.
JM/LJ	
	Explain purpose of the focus group:
JJ	You may have read the participant information leaflet but I would just like to briefly explain a little more about my research to you. There is lots of clinical research going on seeing whether treatments work, they are looking at how good the treatments are at achieving what they intend to achieve. So my research is all about finding out what is important to patients, what they want to achieve from their treatment and therefore what should be included in these research studies. Because often what patients say is important to them is different to what HCPs think. The term used to describe what you want to achieve is outcomes. So today what we are going to talk about is what outcomes matter most to patients who have received pressure garment therapy. You have all experienced pressure garment therapy and therefore I believe that you are the best people to help me with this. Both Jonathan and I have worked with staff at the burns unit at the QE hospital but neither

	of us are clinicians or experts in burns injuries so we may ask you to explain things if we don't understand them. **Does anyone have any questions at this stage?** *Refer to the diagram on the wall* Ideally this is not a question and answer session so when we start I will introduce the following topics for you to discuss as a group: 1. Your experience of pressure garments. 2. What is most important for you to achieve from your pressure garment therapy. 3. What should be assessed in research on pressure garments. Both Jonathan and I may ask questions and take notes.

JJ	*Confidentiality:* This discussion will be confidential. We will not disclose things that are discussed in the group and the way we present findings from the discussions today means that individuals cannot be identified. *Ground rules of the focus group* (to be put up on a flipchart if available): 1. We hope this will be an open discussion 2. There are no right or wrong answers 3. Try to speak one at a time. 4. Listen to others 5. Respect others opinions even if they differ from your own, however if your view or experience is different please do say. 6. I am here to help guide the conversation but we want you to discuss points made by others in the group. 7. Please be mindful that people may have discussed things in this group that they may not necessarily want discussed or shared outside of this group. You may notice some post-it notes on the desk. I will explain about these a little later in the discussion. **Does anyone have any questions?** **Is everyone happy to start the discussion?**

JJ	**<u>Turn on the recorder</u>**

Discussion

It's great to see you all here. For the purposes of the tape and so that we can tell who said what can you please introduce yourself and briefly tell us what motivated you to come to this group today. We'll go around the room this way (indicate direction so that co-facilitator is next). I'll start us off….

I'm Janet and I'm a PhD student here at the University of Birmingham and I'm here today because I think that your ideas will be really helpful for my research.

After introductions:

Firstly, I would like you to tell us how long you have been wearing pressure garments and what type of pressure garment you are wearing.

As you can see on the diagram here, we are going to talk about your experiences of wearing pressure garments

1. Your experiences of pressure garments

a. How did you feel when you were first told about wearing pressure garments?

i. What was your initial reaction?

ii. Had you heard about pressure garments before?

iii. Did you have any concerns or reservations about wearing pressure garments?

b. What did you understand they would do?

	i. Were Pressure garments explained to you? *ii. Were you told what to do?* **c. What were they like to wear?** *i. How did you feel whilst wearing them?* **d. What are the good things about wearing pressure garments?** e. **What are the bad things about wearing pressure garments?**
JM/LJ	Thank you, I think we've had a good discussion about your experiences is there anything else anyone would like to add before we move onto the next topic?
JJ	Is there anything Jonathan/Laura would like to ask? If something does occur to you when the discussion has moved on please jot it down on one of the post-it notes and we can discuss it at the end.

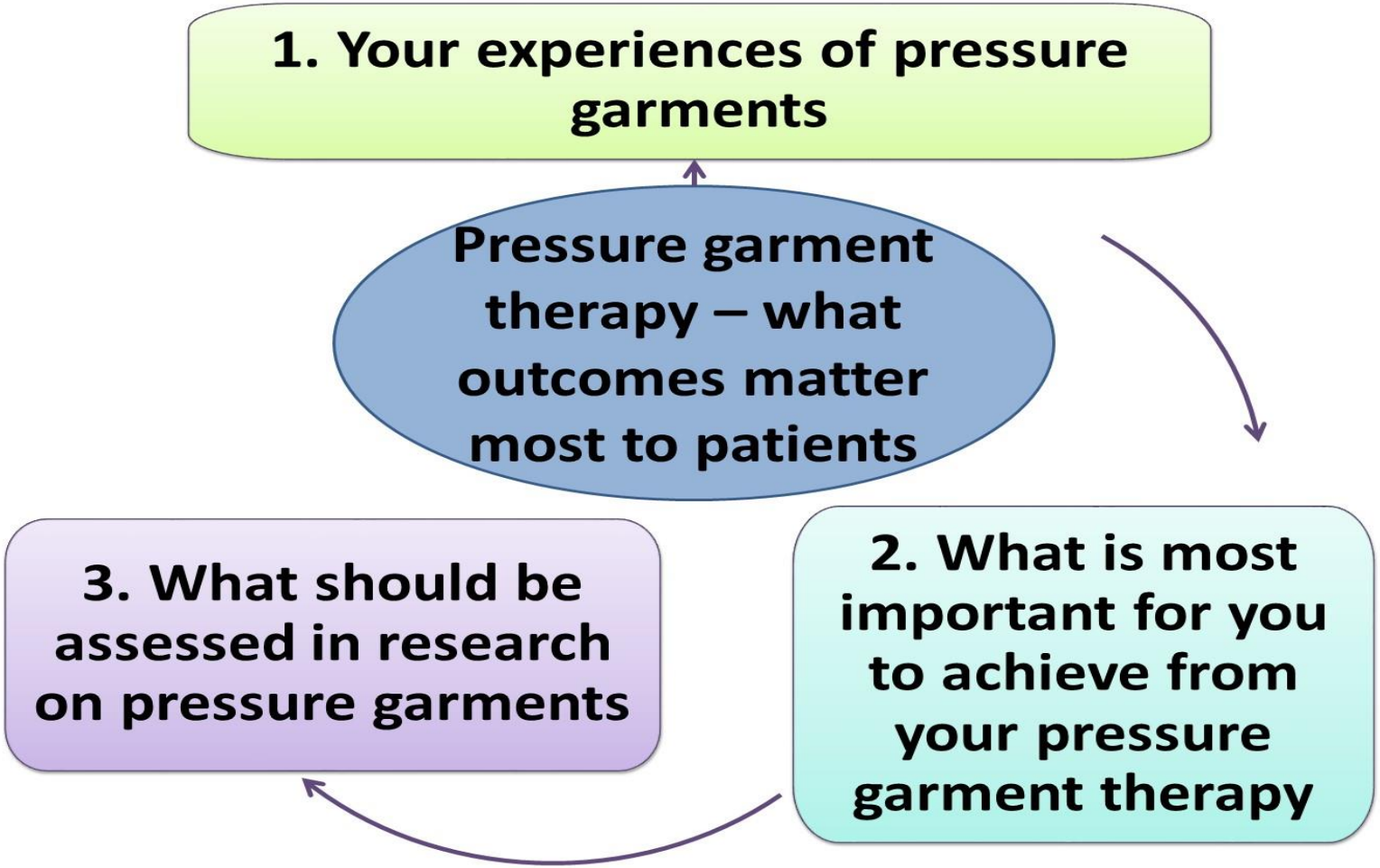
JJ	***2. What is most important for you to achieve from your treatment*** *i. What did you hope PGs would do for you?* *ii. What were your overall hopes for recovery?* *iii. What do you think pressure garments have done for you?* Thank you, I think we've had a good discussion about what is important to you is there anything else anyone would like to add before we move onto the next topic?
JM/LJ	Is there anything Jonathan (or Laura) would like to ask?
JJ	As before if something does occur to you when the discussion has moved on please jot it down on one of the post-it notes and we can discuss it at the end.

JJ	So far we have discussed your experiences of pressure garments and what is important to you about your treatment and recovery. 3. ***What should be assessed in research on pressure garment therapy*** So lastly we come to what to assess in research on pressure garments. Remember at the start I talked about how research is done to find out how effective treatments are. I also explained that it is important that we can feed into that research what outcomes are important to patients because their views often differ to those of HCPs. We may have talked about these already or you may have some different ideas. Thank for your ideas and suggestions.
JM/LJ	Is there anything Jonathan (or Laura) would like to ask?
JJ	So, thinking about where we started and what we were aiming to achieve (refer to diagram) I'll just sum up what we have talked about today (refer to notes on whiteboard). Does anyone have anything else to add? Has anyone written anything on a post-it note?

JJ	**Closing**

	I just have one final thing to ask you: We are also planning to do some of these sessions as an online discussion forum. Rather than talking face-to-face participants would be given access to a specially designed forum. They will be invited to type their responses to questions posed by myself and will be encouraged to interact with other members of the forum. I am interested to know what you think about this idea. Thank you for your time I hope you have found the discussion interesting and informative I know that I have. I would just like to remind you that people have discussed things in this session that they may not wish to be discussed or shared outside of this group.

Appendix 20 – Face-to-face focus group visual guide



Appendix 21 – Online focus group topic guide

Online Focus Group Topic Guide

Version: 1, Date 18/05/2016

What outcomes matter to adult burns patients that have experienced scar management therapy? (The OSCAR study)

Doctoral researcher: Janet Jones

Opening

Thank you for taking the time to participate in our online discussion about pressure garments. If you haven't done so please read the participant information leaflet and the ground rules for the discussion which have been sent to you and are also available on the website.

The purpose of this discussion is to understand the outcomes that are important to you following your scar management treatment. This will include asking you about the treatment you have received and how this has affected all aspects of your life. We would also like to know whether this has matched your expectations and if not what you would like to achieve from your treatment.

I hope that you will find this discussion interesting.

Topics for discussion

- Participants' hopes for the treatment
- Participants' feelings about the treatment
- Whether the participants think the treatment has helped to manage the scarring
- How the burn injury has affected their life (home, work and social)

Closing

Thank you for your time I hope you have found the discussion interesting and informative I know that I have. I would just like to remind you that this session is confidential and should not be discussed outside this chatroom.

We are also conducting some of these sessions as face-to-face discussion groups. I am interested to know if you would have preferred to take part in a face-to-face discussion rather than online or whether you think an individual face-to-face interview would be better. Please also give the reason(s) for your preferred choice.

Appendix 22 - Biography

Biography

I present here a very brief biography of my life experiences and how they may impact on my position as an insider researcher for this thesis. Additionally, I describe how my route to this PhD has not been straightforward or indeed a traditional one.

I come from a white working class background and left school at the age of 16 to provide financial support to my parents. After leaving school, I worked in various business sectors such as telecoms, local government, manufacturing and the NHS. Whilst working at the NHS I decided to further my education and enrolled on an Open University undergraduate course unsure whether I would be able to cope or even achieve this goal. To my surprise, but not to those closest to me, I achieved my goal and came away with a 2:1 in the History of science, medicine and technology. I thoroughly enjoyed by studies and managed to interweave them with raising my daughter as a single mother and working full-time. My degree success led me to a job as a Trial Coordinator at the University of Birmingham, which in turn has led me to undertake this PhD in order to further my research knowledge and skills.

My research involves interaction with participants who have gone through the traumatic experience of a burns accident, which in many cases has scarred them for life. Although I am unable to relate to this particular experience (my outsider

perspective) I feel that I can relate to some of their emotional and symptomatic experiences.

Since birth, I have suffered from eczema, which fluctuates between being reasonable okay to being unbearable. This included appearance, dryness and the itchiness, which when it is particularly sever can almost drive you mad. These are also symptoms experienced by burns patients, which can have a profound effect on their quality of life. When I was 13, I lost all my hair through alopecia, which has never grown back. This had a profound effect on my mental health during my teenage years due in main to the comments and behaviour of others towards me. Several years on I have accepted this is who I am and I try not to let it hold me back from achieving the things I want to do, although self-doubt often reoccurs. To a certain degree these life experiences around physical and emotional feelings are relatable to those experienced by patients recovering from a burns injury and this is my insider position.

Braun and Clarke recommend disclosing your insider/outsider position to the research participants. However, in this case I chose not to disclose my insider position because I did not want it to distract from things that were important to the participants.

Appendix 23 – Reflective note

Focus group 2, 31 March 2017 at 2pm

Reflective notes

Initially only three participants arrived to take part in the focus group. The group started well with everyone contributing however, one member was inclined to interrupt the others and this took a great deal of facilitation. Halfway through the group another participant arrived and this changed the dynamics of the group. The person who tended to talk over the others backed off a little. I found it difficult to know how to deal with the late arrival: I needed to explain the purpose of the focus group and what we had been talking about to the newcomer but I was conscious that I didn't want to spend too much time going over old ground and risk the others losing interest. I think this worked out reasonably well, everyone still seemed to be engaged in the discussion.

I noticed that none of the participants were wearing their pressure garments. Initially R was reluctant for her scar to be on show, she kept her arm under the table. However, as the discussion moved on and the others talked about their scars she became more confident with her arm on show.

To this group the fit and comfort of the pressure garment was very important.

They also talked about the reaction of others to their scars and pressure garments. All agreed they felt more confident wearing pressure garments in public than not: people can see them but don't know what is wrong.

This was a difficult group to facilitate with one member arriving late and another talking over others when they were speaking. This is something I need more experience of.

I think that writing on the whiteboard the items which arose in the focus group was a good way of summing up at the end of each topic and worked well.

Like focus group 1 the majority of the data were elicited from topic 1 “what are your experiences of pressure garments? Members struggled to understand what we wanted from topic 3 (What do you think should be assessed in research on pressure garments) despite explaining outcomes at the beginning of the focus group and again at the beginning of the topic.

Conversation after the tape was switched off (paraphrased)

R getting own independence back is important. It annoys me when others won’t allow me to be alone

C Reiterates this and says he has the same problem

Other notes

R was getting quite annoyed at the over talking at one point

C&R both epileptic and were supportive of each other. Neither had met another epileptic patient who had experienced a burn injury as the result of a fit.

D seemed to be slurring his words and indeed apologised for doing so on a few occasions.

Appendix 24 – Codebook of interpreted outcomes

Oscar study codebook

Outcomes	Description
Scar features	How the scar looks. Hopes for treatment of these symptoms. Success/failure of treatment in relation to these features
Colour	Colour, redness, inflammation
Dry, cracked skin	Skin is cracked and/or wrinkled around the scar
General appearance	General comments about the appearance of the scar. Also includes comments about the appearance of pressure garments
Height and thickness	Flat, level, raised. Skin around the scar area is thick
Scar sensation	Descriptions about how the scar feels
Itchiness	Intensity of itching, Trying not to scratch
Lack of feeling	Includes numbness and pins and needles
Pain	Experience of pain and/or soreness from the injury
Sensitivity	How things feel when touched, hypersensitivity.
Discomfort	Soreness, general comfort issues associated with the scar and/or pressure garments.
Mobility, movement and function	Exercise, walking, being able to carry out everyday tasks and range of movement
Function	The ability to carry out activities and tasks as expected.
Mobility	Being able to move around, walk
Range of movement	The range of movement in the joints
Psychological well-being	Emotional and mental symptoms as described by participants
Anger	Anger, Frustration, Agitation.
Depression	Onset since accident. Mental strain. Having suicidal thoughts.
Fear	Scared of the unknown. Panicky and paranoid. Fear that the same is going to happen to selves or loved ones.

Outcomes	Description
Loss of identity	loss of identity, burn injury defines who they are.
Guilt	Feels guilty about the burden placed on family and friends. Blames self for the accident and feels foolish.
Protection and security	PGs stop clothes rubbing. PGs provide a sense of security from further damage. PGs make the participant feel secure. PGs hide the scar.
Self-confidence	The need to rebuild self-confidence or participants feel confident about themselves.
Stress	Stress, PTSD, worry, anxiety
Support network	The need for good support from HCPs, family and friends.
Trauma	Needing recognition by the health service of the trauma and shock following the accident. Side effects following the accident such as claustrophobia, flashbacks and Post Traumatic Stress Disorder (PTSD).
Vulnerability	Feeling vulnerable to comments from others. Wondering why it happened to them, feeling helpless. Unable to help themselves. Feeling stigmatised by the burn injury.
Returning to a normal life	How patients view returning to "normal"
Getting out and about	The ease/difficulty of getting out following the accident. Taking treatments with you when you go away (heavy)
Driving	Wanting to be able to drive self and not have to rely on others.
Hobbies and pastimes	Wanting to be able to carry on with favourite hobbies. Any barriers to doing this
Acceptance	Injury is now a way of life. Need to put things into perspective. Feels as though they are getting there. Moving on with life
Returning to work or education	Getting back to work/education is important. Participant is back at work or education or has not yet returned
Treatment regime	Lots involved in sticking to the treatment regime. Comorbidities to deal with. problems with ill fitting pressure garments
Daily routine	The daily routine participants have to go through. How time consuming it can be.
Feeling like a burden	Needing help with treatment, to travel to hospital appointments and daily life (cooking, housework).
Frequent appointments	Number of appointments at the hospital and the costs involved (time and money).
Lots to deal with	Coping with multi-morbidities. The cumulative burden of treatment including unexpected side effects i.e. infections. Adherence to treatment.
Recovery time	Awareness of how long recovery will take.

Appendix 25 – Additional supporting quotes

Theme	Interviews	Face-to-face focus groups	Online focus group
Features of the scar			
Colour	*"Yes, as long as it went back to skin coloured or as near as then I wouldn't be too bothered"* CA06. *"I don't think it (redness) will change too much now ……...I'm not bothered now"* CA05.	*"Redness normally takes time like they say as scars heal. It's like me cheek they're quite red now compared to my complexion, but it's like my OT said to me that will take time anyway, talking 18 months, two years' time"* FG2 participant 4	*"The creams and silicone gel has reduced the redness to some extent".* Pine, online focus group
Dry, cracked skin	*"But when I get the support off for a period of time why does it start wrinkling up with little bits and pieces?"* EG03.	*"My hand hurts if I… when I shower it's horrible, the skin gets very dry".* FG3 participant 3	*"Difficult to tell if the silicone gel has been doing anything but the scar isn't dry so I guess it has been doing its job in keeping moisture in".* Maple, online focus group
General appearance	*"it really looked horrible, so I am amazed in the process of massaging and the pressure garment how it looks now, and they have said that it may still continue to fade"* EG02.	*"I would never imagine back then two and a half years ago that I would be how I am now. I look at my legs and I think I appreciate things a lot more, the things that I took for granted. So I think pressure garments have*	*"I wear specialist camouflage makeup at times, when I can, but it isn't always possible or practical".* Pine, online focus group

Theme	Interviews	Face-to-face focus groups	Online focus group
	"I ain't bothered what it looks like" QA02. *"My husband and I were really shocked at the difference, it had almost shrunk"* EG02. *"I've still got the cross hatching, and I think that will always be…"* CA07.	*definitely helped"* FG1 participant 2	
Height and thickness	*"It's raised, and that's causing the itching and the sensitivity"* EG02. *"I believe the gloves definitely helped. To look at my hands now the scars look nice and flat, and they're soft, and I believe that the pressure garments worked"* CA01. *"I thought they would help with the flattening of the scar from what I read. Initially it did, but not after a while, so it didn't actually make that much improvement after a while"* EG01.	*"It's (pressure garments) working, I've got to give it that because the scars that are on my face are definitely gone down to what they were to be honest" FG1 participant 1*	*"I am hoping that the pressure garment will flatten the scar and soften it up. It does seem to be doing that but slowly".* Maple, online focus group *"I definitely noticed the garment would flatten out the scar tissue. As I would not wear my facial mask out much during the day, I noticed a drastic change in how raised the scar on my face was from when I started the day and took the make off, to a few hours later it would be a lot more bumpy".* Birch, online focus group

Theme	Interviews	Face-to-face focus groups	Online focus group
Sensation of the scar			
Itchiness	*"In the summer it sometimes gets itchy and swells"* QA01. *"It just itches, like polyester or whatever it is, so most of my clothes that I've got I've got rid of and buy cotton, whether its short sleeves, long sleeves or three quarter sleeves, I can't stand it its horrible"* EG03. *"It's weird, I've got two places that itch like crazy, and I try not to scratch them, and I end up rubbing them together"* EG06. *"But then after that first year itchy, every now and again, not all the time, and it still does it now, but not something that would bother me I don't think, just every now and again I go that itchy"* EG08.	*"The itching was just so awful I was starting to scratch all over my body, and I thought if I don't stop this…"* FG3 participant 4 *"She told me… [consultant] told me not to scratch it again which even though subconsciously you do scratch anyway, you can't help it" FG2 participant 1*	
Lack of feeling		*"I've got no feeling in those two fingers and the thumb, I have a permanent numbness and just a*	*"Touching sandpaper, everything I touched felt like sandpaper, my face, the arms,*

Theme	Interviews	Face-to-face focus groups	Online focus group
		bit of pins and needles in them" FG1 participant 3	*everything, my legs, just felt like touching sandpaper"* FG1 participant 1
Pain	*"Yes, it's not an ache as in muscle ache, it was an ache as though the... I don't know how to describe it really, but it was as though the skin was very sensitive and being stretched to its limit"* CA06. *"It was so sore, so painful, what else? Well it's not so much painful, you know like a pulse? It was throb, throb, throb"* EG03. *"And I thought you don't realise how much pain I'm in at times, but it's no point just limping about everywhere looking for sympathy"* EG05.		*"By treating my burns scars I ended up with other scars on my body from where the grafts were taken and so feel I need to hide these too. And split skin grafts are so painful".* Pine, online focus group
Sensitivity			
Discomfort	*"I think I've come to terms basically with it now, but I've got what I've got. I'd like to get the*	*"These are still tight now, and that's two and a half years ago"* FG1 participant 3	

Theme	Interviews	Face-to-face focus groups	Online focus group
	colouring down a little bit, and maybe a little bit more... the tightness is not too bad, it seems to be more so when I'm sitting down for a long period, or if we drive somewhere for a couple of hours and I get out of the car, I can feel it pulling the back of my legs, the actual scars". CA09 *"On the occasion it still feels a little bit tight, but it's just normal really, but I just keep on top of the creaming and then I'm back to doing everything I was before"* EG07.	*"In parts of mine I do get stabbing pains, lately it's been on that really thick part there, it's actually really hard, and it does seem to be getting tighter, I don't know why, but I do get…"* FG2 participant 2	
Mobility, movement and function			
Function		*"They're pressing here and you've got no way of bending your thumbs and fingers, and if you're out shopping there's no way you carry a shopping bag."* FG2 participant 3	
Mobility	*"I thought the y(PG) were very good, not only did they help reduce the swelling, definitely smoothing out the scars, and*		*"In terms of the garments, I expected it to thin out the scar tissue and therefore possibly help my mobility and comfort*

Theme	Interviews	Face-to-face focus groups	Online focus group
	also providing the support on where I've lost all the muscle and the strength in the tendons and stuff, it gives you that bit of extra support so that you can move". EG06		*levels, which I guess is what I expected from the overall treatments".* Birch, online focus group
Range of movement		***Facilitator What do you mean by until it works better so that you can?*** *"Well you've got the same movement as what you did have before, or close to it".* FG1 participant 1	*"I was burnt on my dominant hand/arm and it remains fairly weak and limited range of movement. So things I find hard (but aren't limited to, as the list would never end) include: Lifting anything that is heavy, Opening bottles and jars etc., Cutting food up, Writing for more than about 5 minutes, or anything that used my hand/arm makes it really achy and painful really quickly. I can't do things like play tennis anymore. I was studying photography when I had my accident and I now struggle to hold the weight of my camera".* Pine, online focus group
Psychological well-being			

Theme	Interviews	Face-to-face focus groups	Online focus group
Anger			
Depression			
Fear		*"I've got a paranormal about the grandkids hurting themselves, I'm for ever telling them not to move or not to jump off things. It's made me really funny sort of thing like that it has".*FG1 participant 1	
Loss of identity	*"Mentally I think it puts a big strain on you, for a long while I used to look in the mirror and I used to stand and cry because I used to think I don't want this"* CA04.		
Guilt	*"I felt guilty because I knew I was going to be burdening my grandparents with this"* QA08.		
Protection and security			
Self-confidence		*"There's only so much you can shut out and then it creeps back in then, and that's where the lady said herself it doesn't*	

Theme	Interviews	Face-to-face focus groups	Online focus group
		matter how much you try and polish it over or skin colour or whatever it is, wear a glove, even if it was invisible, you still feel a lot different, no matter how much people recognise it or they don't". FG2 participant 4	
Stress			
Support network	*"But the searing heat we had yesterday this is where I have to have people normalise it for me, because I can't remember how I would have been pre-accident, whether I would have been dripping wet anyway"* CA07.		
Trauma	*"Yes, I was back at work, and I wasn't sleeping, a couple of months ago, I was just having flashbacks all the time"* EG05.	*"It was an electrical explosion I was involved with and it blew me back six/seven feet clear across a room, so my first part was I was unconscious for the first part, and I've got a lot of memory loss due to it. The week before and something like that is gone, and part of the day is gone, but little bits come back, and as I say talking to people who are there and they fill it in, and flashbacks*	

Theme	Interviews	Face-to-face focus groups	Online focus group
		and this, that and the other, and found that's just a part of my memory coming back". FG3 participant 2 *"You can see I've seen the clothes I was wearing, so I know that's why you say… I know I had plans with that guy with the big scythe that day"* FG3 participant 2	
Vulnerability	*"We stood out the front of this shop… I had my shorts on and this old lady walked up and said 'oh cor they don't look very sharp do they?'… and I felt so conscious then"* CA05.	*"I would have rather worn mine than people looking at my burn, because I do get a lot of people look at it. I was on the train here actually and it was absolutely packed and I just saw this girl staring it for ages, and then I caught her, well she looked up at me and I'm just there yes it's a scar, just stop it. It makes me feel more uncomfortable when people look at it, because they look at it oh what the hell is that?"* FG2 participant 2	*"I used to explain to people what happened when they asked but I'm so over doing that now because I don't owe them an explanation. Explaining to people you've never met before and will never see again to me just seems pointless and intrusive. It also takes up a lot of time which I do not have when I am working haha".* Maple, online focus group

Theme	Interviews	Face-to-face focus groups	Online focus group
		"I found eventually after a couple of months of using (pressure garments) that's security from… and didn't know I was getting security from them, when I look back I must have done. It must have settled me a lot more mentally; I remember I wouldn't go out without it" FG1 participant 3.	
Returning to a normal life			
Getting out and about	*"We had the creams in a rucksack…….. and I was absolutely terrified they were going to notice the creams and not let us in or ask us to remove them and get rid of them"* CA07.		
Driving	*"Unfortunately after a couple of months it was healing but it was getting very painful, and it was starting to tighten up, and really stopped me…I couldn't drive while it was like this anyway"* CA02		

Theme	Interviews	Face-to-face focus groups	Online focus group
Hobbies and pastimes	*"I want to be with my dogs, my dogs are my life, it made me get out, it made me walk, it made me do something twice a week even when I was working, and it did"* CA05.		*"Before my accident occurred I would regularly lift weights and go to the gym, and while I eventually got back into those activities, it was very difficult in the beginning as holding weights was a struggle".* Birch, online focus group
Moving on	*"No, because well obviously my passport photograph didn't look nothing like me, and also... my passport didn't look like me and I had no identity because everything in the fire, every qualification, every nice bit of clothes, my daughter's pictures, my computers with all my pictures on, everything was gone, kaput".* QA01	*"Yeah, take everything in a little bit at a time, don't go trying to run before you can walk type thing, because I thought if you try to do that you're going to get knocked backwards, and the worst part is if you get knocked back further than where you were to start with so you want to take those small steps, so one little knock back is okay, but if you get a major knock back you can be thrown back to the start again, and that's our experience is you're getting pushed through".* FG3 participant 2 ***Facilitator So it's finding a new role is that…***	*"I never get angry though personally, and I think I have become more used to it. It doesn't get to me in the way that it did at the beginning".* Pine, online focus group *"I know that I will never be completely the same as I was before the burn injuries and don't expect that as some people do, but I hope to get as close as possible in terms of looks and comfort level".* Birch, online focus group

Theme	Interviews	Face-to-face focus groups	Online focus group
		"Yeah, a new… not entirely because you go on, a lot of your life stays the same, it's accepting the new body isn't it really?" FG3 participant 3	
Returning to work or education	*"I actually work offshore now on an oil rig for two weeks at a time, so it's the same industry but a different location"* CA09.		*"The main things that I can't do are eat, drink and talk properly. The mask is very restrictive so I find I can't pronounce words properly. This was really annoying when it came to my degree because I study Spanish and Portuguese. These languages have different sounds to English and use different muscles etc. so being restricted in the mask made it difficult to get the right accent".* Maple, online focus group
Treatment regime			
Daily routine		*"Take it off to wash your hands, you take it off to go to the toilet, everything like that because you wash your hands after, and you've got to put the glove back on, that could be a pain sometimes"* FG.3 participant 2	

Theme	Interviews	Face-to-face focus groups	Online focus group
Feeling like a burden	*"I have to wash my feet twice a day, my sister cooks and cleans for me, and she cleans my room for me and all of that"* QA05. *"Yes, my dad would help me get dressed in the morning, and obviously get into the bath"* CA06.		
Frequent appointments	*"Just constant hospital. You have one thing done, then there's something else got to be done"* QA02. *"Yes it was an hour run, because I used to have to be there a good half an hour before, so I used to have to have the morphine again just to do my dressings. It was quite an experience"* EG05.		
Lots to deal with	*"One of them used to roll down and if I didn't get it right where*	*"You just have days when normally I get up and out and my carer she knows me very well*	*"Time is definitely an important factor in recovery. The tissue takes a long time to heal itself,*

Theme	Interviews	Face-to-face focus groups	Online focus group
	the burns were it would dig into my flesh" CA03. *"If it's hot I daren't go out in the sun without it being covered up"* EG03.	*now, but she will prompt me, 'make sure you're getting them garments on'. I just have days where I just say that's enough"* FG2 participant 4 *"Wear them every… all day apart from when you have a shower, and I have put, and I still put moisturising cream on and massage"* FG1 participant 2 *"I didn't mind a bit, because they were such a relief, because they were comfortable when they were on, so I was tempted to wear them for the 24 hour straight off. So I've gone along doing that all the time"* FG3 participant 4 *"Yes, I still do to be fair, which is very unusual for me, normally I get fed up give a week, or two weeks or whatever, but I stuck to it"* FG1 participant 3 *"I'll tell you thick plastic, metal bars on the bus, your hands are literally sliding with pressure*	*as much as I would love it to instantly repair. I guess it's a combination of time, patience, and commitment to things like the pressure garments and the massaging, physio etc."* Pine, online focus group *"23 hours a day, an hour off for washing and massage therapy. I also used (& still use) silicone gel that I rub in to my scars. I was meant to have 2 of the garments at a time so I could wash one, wear one, but this didn't happen in reality because the burns unit were too busy and overrun to make them so often there were long periods where I didn't wear them as it was being washed and dried".* Pine, online focus group *"As for garments I think they need to be more practical. So maybe looking at the material so it dries quicker, so if it does get wet which mine always did by the hands then you weren't stuck with leaving on a wet*

Theme	Interviews	Face-to-face focus groups	Online focus group
		garments on, you can't get a grip" FG2 participant 3	*garment that took hours to dry and in the meantime made your skin really sore. As Birch said, looking at the complications implications etc. of wearing these items (beyond "your scar will heal better") is important. Being able to brush your teeth, wash your hands etc. whilst also trying to keep a garment on for 23 hours a day just doesn't happen!"* Pine, online focus group
Recovery time			

Appendix 26 – Co-authored paper

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Trials

METHODOLOGY Open Access

The use of qualitative methods to inform Delphi surveys in core outcome set development

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Abstract

Background: Core outcome sets (COS) help to minimise bias in trials and facilitate evidence synthesis. Delphi surveys are increasingly being used as part of a wider process to reach consensus about what outcomes should be included in a COS. Qualitative research can be used to inform the development of Delphi surveys. This is an advance in the field of COS development and one which is potentially valuable; however, little guidance exists for COS developers on how best to use qualitative methods and what the challenges are. This paper aims to provide early guidance on the potential role and contribution of qualitative research in this area. We hope the ideas we present will be challenged, critiqued and built upon by others exploring the role of qualitative research in COS development.
This paper draws upon the experiences of using qualitative methods in the pre-Delphi stage of the development of three different COS. Using these studies as examples, we identify some of the ways that qualitative research might contribute to COS development, the challenges in using such methods and areas where future research is required.

Results: Qualitative research can help to identify what outcomes are important to stakeholders; facilitate understanding of why some outcomes may be more important than others, determine the scope of outcomes; identify appropriate language for use in the Delphi survey and inform comparisons between stakeholder data and other sources, such as systematic reviews. Developers need to consider a number of methodological points when using qualitative research: specifically, which stakeholders to involve, how to sample participants, which data collection methods are most appropriate, how to consider outcomes with stakeholders and how to analyse these data. A number of areas for future research are identified.

Conclusions: Qualitative research has the potential to increase the research community's confidence in COS, although this will be dependent upon using rigorous and appropriate methodology. We have begun to identify some issues for COS developers to consider in using qualitative methods to inform the development of Delphi surveys in this article.

Keywords: Core outcome sets, Qualitative research, Delphi, Methodology, Clinical trial

Background

Randomised controlled trials (RCTs) typically provide robust evidence, which can be used to inform clinical practice and health policy [1]. The outcomes measured within a RCT allow the benefits (or harms) associated with an intervention to be quantified. Outcomes measured in RCTs need to be useful and relevant to a range of stakeholders including patients, clinicians, policy-makers and regulatory agencies [2, 3]. Outcomes are often identified, chosen and specified a priori by the trial management team (traditionally, researchers and clinicians), sometimes with input from patient and public contributors [4].

The use of numerous varying trial outcomes across a research field or clinical area can be problematic. First, this can reduce the ability of systematic reviewers to synthesise results. The most accessed Cochrane reviews of 2009 all reported problems with heterogeneity of outcomes [5], while similar problems were found in an

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analysis of the ClinicalTrials.gov database [6]. Second, lack of an accepted standard can lead to reporting bias, based on the significance of the findings [7–9]. Furthermore, outcomes that are selected solely by researchers or clinicians may not hold relevance for other stakeholders, such as patients, carers or other decision-makers.

These problems can be addressed through the development of a core outcome set (COS) for use in a clinical area or research field. A COS is a standardised collection of outcome domains that should be reported in all controlled trials within a research area [10]. Trialists are not restricted solely to these outcomes and can use additional outcomes to those in the core set; therefore, a COS marks the basic requirement for which outcomes need to be measured and reported in all studies in a field [11]. Furthermore, COS development is typically focussed initially on *what* to measure with subsequent consideration needed of *how* to measure those core outcomes. In this paper we use the term 'outcome' to refer to outcome domains.

The rate of development of COS has increased over the last 10 years, to the point where close to 20 new COS were published in 2013 [12]. Core outcome sets have been developed for use in a wide variety of clinical specialties [13], including cancer, rheumatology, neurology and cardiorespiratory research; for use with different populations, such as adults and children; and for use specifically in pharmaceutical or surgical research. The development of COS is attractive to funders such as the National Institute for Health Research (NIHR) and others, as it increases the chance that the 'value of their investments will be greater than the sum of the reports' through the increased ability to synthesise and compare results, as well as a greater assurance the that outcomes used in funded studies will be of relevance to stakeholders [14].

The methods used in COS development exercises are important as they may influence the final COS [3]. Development of a COS can comprise several phases, often starting with a systematic review of the published literature to identify what outcomes have been measured in previous trials or studies in a clinical area. This may generate a 'long list' of candidate outcomes for a COS. Consensus methods, such as simple face-to-face meetings, nominal group techniques and, increasingly, the Delphi survey, may then be used to reach agreement about which outcomes are 'core' [3, 13]. The Delphi is often followed by a consensus meeting of key stakeholders to agree the final COS. Qualitative research can be used in several of these phases, but our main focus in this paper is to outline the use of qualitative research to inform Delphi surveys in COS development.

A Delphi survey is a sequential process through which the opinions of participants are sought, usually anonymously [11]. Participants in a Delphi survey do not interact directly; rather, after the completion of each round of questionnaires, the collated group responses are fed back to participants. In this way, equal weight is given to all those who participate and the risk of an individual or group of individuals being overly influential or dominant in the process is reduced [15].

Of the 227 COS studies published up to the end of 2014, 38 (17 %) included the use of Delphi surveys, while the rate of use in ongoing studies appears to be higher still. The majority of COS studies using Delphi survey will use a modified rather than a traditional Delphi. In a 'traditional' Delphi the outcomes of potential importance would be identified solely in the first round of the Delphi through the use of an open text question [16]. In modified Delphi surveys in COS development, a 'long list' of outcomes is identified prior to the Delphi survey, often, as noted above, through a systematic review of outcomes measured in previous trials.

However, a list of outcomes identified through such systematic reviews may largely reflect outcomes that researchers have thought important to measure, particularly where trials predate the recent emphasis on patient and public involvement (PPI) in the design. Patients, carers and healthcare professionals might differ from researchers in what outcomes they see as important. Relying solely on systematic reviews of previous trials may lead to outcomes that are important to patients and other stakeholders being overlooked. Trialists need to have confidence that the perspectives of all relevant stakeholder groups have been heard and that their views of important outcomes are incorporated into the Delphi and, depending on the results of the Delphi, into the final COS. To address this COS developers have recently incorporated qualitative research into the development process to help ensure that the outcomes in a COS are important to the whole community of stakeholders, including patients [13]. Often this has involved qualitative data collection methods such as focus groups and one-to-one interviews with patients, carers and healthcare professionals [17, 18]. However, little methodological guidance or precedent is available about how qualitative research can best be used to inform this component of COS development [19, 20].

Aim

This paper has two aims. First, we discuss the potential roles for which primary qualitative research may be used in the pre-Delphi stage of the development of a COS. Second, we highlight considerations for conducting primary qualitative research in the pre-Delphi stage of a COS development based on our experiences of using qualitative research in three COS development processes (Table 1).

Table 1 Description of studies used to inform this paper

	PARTNERS2 [30]	CONSENSUS [31]	mOMEnt [32]
Study title	Core outcome sets for use in effectiveness trials involving people with bipolar disorder and schizophrenia in a community-based setting	CONSENSUS – squamous cell CarcinOma of the oropharyNx: late phaSE cliNical trialS; core oUtcomeS	mOMEnt – management of Otitis Media with Effusion in cleft palate: protocol for a systematic review of the literature and identification of a core outcome set using a Delphi survey
Qualitative data collection method	Focus groups and one-to-one semi-structured interviews, with prompts to cover key discussion points. Topic guide used as an aide memoire and iteratively updated	One-to-one or three-way semi-structured interviews with patients and their carers. The topic guide comprised prompts to ensure key topics were explored and was iteratively developed	Conversational style interviews with parents including prompts to discuss topics identified from relevant literature. Developmentally appropriate interviews with children
Participants	Bipolar disorder and schizophrenia service user and their carers and healthcare and research professionals working in this area	UK and US patients treated for oropharyngeal squamous cell carcinoma (a type of head and neck cancer) and their carers	Parents of children with non-syndromic cleft palate (including cleft lip and palate) between 0 and 11 years of age, who had a current or past diagnosis of OME, and children themselves aged 6–11 years
Ethical approval	Ethical approval for the study has been sought and granted from the National Research Ethics Service (NRES) West Midlands – Edgbaston (reference number 14/WM/0052)	Ethical approval for this study was sought and granted in the UK by the Liverpool Central Research Ethics Committee (reference 12/NW/0708). Approval at the University of Texas MD Anderson Cancer Center (Houston, TX, USA) was provided by the Institutional Review Board (protocol number 2013–0285)	Ethical approval for the qualitative interviews with parents and children was sought and granted by the National Research Ethics Service – NRES North East Committee – Greater Manchester East (reference 11/NW/0586)

The PARTNERS2 COS development is part of a larger NIHR-funded project titled: PARTNERS2: Development and pilot trial of primary care-based collaborative care for people with serious mental illness [33]. The mOMEnt COS development was part of a larger NIHR-funded project titled: The management of Otitis Media with Effusion in children with cleft palate (mOMEnt): a feasibility study and economic evaluation [21]. The CONSENSUS study was conducted by Aoife Waters as part of a PhD, supported by the Medical Research Council via the North West Hub for Trials Methodology Research

This paper is not intended to be prescriptive; rather it looks to provide early guidance, which we hope will be challenged, critiqued and built upon by others exploring the role of qualitative research in COS development. We conclude by identifying a number of areas where future research may be beneficial to COS developers.

Results and Discussion

The discussions and advice provided in this paper are based upon the experience of authors in developing three COS in different research areas, with differing participants and using different qualitative data collection methods. Box 1 summarises the COS developments which have been drawn upon.

The role of qualitative research in core outcome set development

As noted above, qualitative research can be used in the pre-Delphi stage of a COS development for a number of purposes:

1. Identification of outcomes that are important to stakeholders
   Qualitative research allows COS developers to explore the views of patients, healthcare professionals and other stakeholders in order to inform the development of a 'long list' of potential outcomes. The discursive nature of qualitative research enables participants to explain important features of conditions and treatments in their own terms rather than requiring them to engage with a discourse of 'outcomes', which is likely to be unfamiliar to those outside clinical research. If conducted appropriately and rigorously the qualitative research should afford stakeholders the opportunity to explore and identify outcomes of importance. In turn, this should promote COS developers' confidence that *all* potentially relevant outcomes have been included in the first round of the Delphi survey. In doing so, stakeholders have the opportunity to set the agenda and potentially identify outcomes that researchers may not have anticipated. For example in mOMEnt, participants emphasised psychological as well as social consequences of impaired hearing, including frustration and behavioural problems in children. This contrasted with the limited reporting of these outcome domains in the literature; of the 49 papers identified in the mOMEnt systematic review, two included outcomes related to psychosocial development and six included outcomes related to behaviour [21]
2. Facilitate understanding of not only which outcomes are important, but crucially why they are important
   Qualitative research with patients, carers and other stakeholders can allow a greater understanding of why an outcome is of importance. For example, in PARTNERS2 employment was found to be an

important social outcome for many people recovering from serious mental illness, and was identified in both the literature review and primary qualitative research. However, the qualitative research allowed us to understand that suitable employment was more important than employment per se and that its importance stemmed from the financial security, meaningful role, structure to the day or the connectedness which attending a workplace can allow. By illuminating the context in this way, qualitative research can ensure that meaningful and accurate outcomes are taken forward into the Delphi survey and brief yet informative descriptions to accompany outcome names are developed to help to ensure that participants can interpret a Delphi survey. Furthermore, findings from qualitative research may help to inform discussion at the later consensus meeting (particularly if there are disagreements among stakeholders), facilitating agreement on the final set

3. Determining the scope of outcomes
   Qualitative research may also allow the scope of outcomes to be defined in a way which holds most relevance to stakeholders in the Delphi. Take the example of quality of life, which is a frequently measured and reported outcome in trials. There are numerous different conceptualisations of quality of life that can be measured, varying from broad definitions, such as global quality of life, capability or well-being, to narrower definitions, such as health-related quality of life or disease-specific quality of life. Furthermore, within health-related quality of life, there are subdomains of physical functioning and psychological well-being. Qualitative research can be used to delimit the scope of the domain and ensure that the breadth of domain taken forward to the Delphi is appropriate
4. Identification of appropriate language for use in a Delphi survey
   The language used to describe outcomes in clinical trial publications may differ markedly from the language used by patients, carers and other stakeholders. Qualitative research that identifies and describes outcomes using participants' own narratives can help COS developers to label and describe outcomes in ways that make sense to the stakeholders participating in the Delphi survey. This is important to ensure a Delphi survey is accessible. For example, based on qualitative findings the research team may choose to describe the outcome of isolation as 'feeling cut off and distant from friends' or the outcome of aggression as 'getting wound up, angry or lashing out'
5. Comparison with other stakeholder data or alternative sources of outcome data
   Finally, outcomes derived from qualitative data collected from different stakeholder groups, such as service users, carers and healthcare professionals can be compared within the study to understand areas of discordance. When used in combination with a systematic review of current outcomes this can allow the COS developers to assess whether the 'standard' outcomes used in trials in that research area are inclusive of the outcomes that stakeholders think should be measured. Or, whether the outcomes currently used in a research area may be missing important domains and should be supplemented when taken into round 1 of the Delphi survey. For example, in PARTNERS2 'symptoms' was identified as an important outcome by service users and carers, healthcare professionals and through the review of literature. However, a clear area of discordance was found whereby service users emphasised 'living with existing symptoms' as important, while the healthcare professional data and the review data focused on 'symptoms' reduction'. In this case, both outcomes are being taken into the Delphi, with correct terminology and descriptions used to ensure the differences in the two domains were evident to Delphi participants.

Deciding when qualitative research might not be needed?

As discussed above, qualitative research may allow the views of a broad range of stakeholders to be included in the development process of a COS and facilitate a move away from researcher-only selected outcomes. However, qualitative research can be resource-intensive; both in terms of time and costs and the requirement for specialist input from qualitative experts. COS developers may want to consider whether such work is needed in the particular clinical area for which they are developing the core set. Developers may want to consider the following points: What is the level of PPI in the research area? If there has been a high level of PPI input into relevant trials and research studies, it may be reasonable to assume that outcomes in the area already reflect the perspectives of these stakeholders, although this may be challenged on the grounds that PPI is not *research*. Developers might also want to explore whether there are existing qualitative datasets that could help to identify outcomes of importance to stakeholders. If relevant studies have been conducted in the area, it may be possible for these data to inform the COS development through secondary analysis. How challenging is the phrasing of outcomes in the Delphi thought to be? For populations or areas where participants are likely to be particularly sensitive to the wording of outcomes, such as children or end of

life care, the extra investment may be beneficial to ensure the wording is acceptable and appropriate. These are some points which developers may want to consider; however, this is not an exhaustive list and other considerations may be important.

Challenges in using qualitative research to inform the development of core outcome sets

Which stakeholders to include?

It is important to consider which stakeholders to include as participants in qualitative research to best inform COS development. Being a participant in a qualitative study demands no prior knowledge of concepts such as 'outcomes' and no understanding of research processes or the rationale for COS (see section below on discussing outcomes). Therefore, qualitative data collection methods are appropriate when working with stakeholder groups such as patients, carers and healthcare professionals for whom such topics may be unfamiliar.

Patients have valuable first-hand experience of living with the illness and receiving treatments and knowledge about which outcomes are important to them. Healthcare and health research professionals may have experience of treating a number of patients or observing a number of research projects and, therefore, understand how an illness manifests itself in different individuals or the different treatment effects in individuals. Other stakeholders such as carers, who are typically spouses or family members, can provide useful perspectives as 'involved witnesses'.

While our experience indicates that patients, carers and professionals tend to identify some similar outcome domains as important, there have also been some differences. For example, in PARTNERS2 when talking about physical health outcomes patients identified broad areas such as weight gain and reduced physical activity; whereas professionals talked about specific clinical outcomes, such as diabetes and blood pressure. Or, when discussing social outcomes, such as being able to participate in a work environment, healthcare professionals identified the ability to work as an important outcome; whereas patients and carers identified subtly different outcomes of participation in work that is appropriate to their condition (e.g. flexible working), and participation in a role that made them feel valued, as important outcomes.

There are indications from the broader literature that the differences we found between the outcomes that stakeholders identify (and the added value of including patients and carers) are widespread in this type of study. Qualitative studies have found that patients may prioritise different outcomes to healthcare professionals [22, 23] and may also identify additional important outcomes [24].

Sampling

The pre-Delphi stage of the development of a COS needs to identify outcomes that are relevant to all stakeholders. A number of studies of qualitative outcomes have reported difficulty accessing a broad range of participants [17, 22, 24]. Therefore, it is important that the sampling strategy facilitates access to patients, carers, professionals and other participant groups who have experience of the illness for which the COS is being designed. If a key aim of pre-Delphi qualitative research is to ensure no outcomes are overlooked, there is a strong case for using a sampling strategy designed to identify a maximum variation sample, as this would be more likely to identify the wide range of outcomes of interest.

Purposive sampling can be used to recruit heterogeneous maximum variation samples, where people differ by select characteristics [25]. This allows participants to be selected based upon characteristics which might be anticipated to influence the outcomes they perceive as important [26, 27]. Parents of children of all ages in the mOMEnt study identified hearing as an important outcome. However, their concerns about hearing differed between parents of preschool children (0–4 year-olds) who focused on speech and language; parents of young primary school children (5–7 year-olds) who emphasised effects on social interaction; and parents of older primary school children (8–11 year-olds) who were concerned about social interaction and educational performance [21]. These differences highlight the importance of including variation in a sample, in this case diversity of age and development of children.

Qualitative samples are normally smaller in size than quantitative samples, as quantification of incidence is not the focus of this research. Rather the purpose is to collect rich data that allows in-depth exploration and understanding of different research questions [28]. Normally there will come a point of diminishing return when new interview or focus group data cease to contribute to the analysis, and the research team will decide to stop data collection (the point of conceptual saturation). In the PARTNERS2 interviews with healthcare and research professionals this was noted after 14 interviews, with a further two interviews conducted to check that data saturation had been reached. A larger sample size may be required if particular diversity is needed in some characteristics. For example, as well as sampling participants from both the US and UK, the CONSENSUS study aimed to include a diverse group of patients in terms of sociodemographic, disease and treatment characteristics and, therefore, recruited over 30 patients and their carers. The mOMEnt study included a range of three cleft malformation types (palate only or in combination with either unilateral or bilateral cleft lip) and four treatment pathways (ventilation tubes, hearing aids, both, or

watchful waiting) resulting in a qualitative sample of 37 children.

Discussing trial outcomes

Qualitative research in the early phases of COS development will be focused on identifying outcome domains that are important to participants. Our experience suggests that the concept of an outcome can be rather obscure and challenging for patients, carers and other stakeholders to engage with. Patients and carers cannot be expected to be in a position to engage meaningfully with questions such as 'what outcomes do you think we should measure in a trial of treatment for your illness?' In the mOMEnt study parents did not respond readily to the notion of 'outcome'. Therefore, parents were prompted to consider what they thought an intervention should achieve (Table 2). Despite this two parents did not distinguish between process (for example 'good aftercare') and outcomes. In the PARTNERS2 we also found that some healthcare professionals, researchers and commissioners also struggled to discuss outcomes directly. Our experience is likely to be reflective of challenges experienced by the broader research community, with a number of studies reporting similar challenges [17, 22].

To address this, careful consideration needs to be given to how outcomes are going to be elicited and discussed when designing qualitative research [29]. Normally this planning would involve consultation with relevant patient groups in order to inform the design of the research. Further consideration and consultation will be needed when developing the topic guide or interview schedule, when planning the prompts to be used and when iteratively developing these over the course of semi-structured interviewing to expand and explore participants' accounts. Encouraging a discussion of how an illness has affected a person's life, which parts of their life they may perceive to have lost and what things they hope to gain through treatment/care was found to be a fruitful way of approaching the discussion in all three of the studies used as examples in this paper. In CONSENSUS one-to-one interviews allowed patients to provide a chronological narrative of their lives as they underwent treatment and beyond. Over the course of their interviews patients spoke of how outcomes that were important early in treatment sometimes differed to those that became important at later stages. Interviews for the mOMEnt study commenced by inviting parents to tell the story of their child's otitis media with effusion (OME) (or 'glue ear'). These accounts provided narratives of the context of experiences of the condition and interventions and included implicit references to outcomes. As the interview progressed the participants were asked to discuss outcomes more explicitly. While in PARTNERS2 participants were encouraged to think back over how their illness had changed their lives and to discuss their goals in living with their condition. Later in the interview participants were encouraged to think about these changes and goals in terms of research outcomes. These may be reflective of similar approaches taken by other studies. For example, a qualitative study by Allard et al. to identify key outcomes for children with neurodisability reported discussing outcomes by asking parents and carers about 'aspects of health' and using a visual aid in the discussion with children [17]. Similarly a qualitative study building the basis for a COS in rheumatoid arthritis asked patients about how they know when a intervention is working, what 'returning to normal' meant to them and what makes them feel well [22]. For all studies used as examples herein, allocating time to these early discussions in focus groups and interviews helped to identify outcomes of relevance and

Table 2 Questions and prompts used by authors to discuss outcomes

Discussions with patients	Discussions with healthcare/researcher professionals
PARTNERS2 'I would like you to think about how your mental health problems have changed your life and what you have lost because of them.' 'This time rather than thinking about what you have lost, I would like you think about what your goals are in living with your symptoms.' 'Since your diagnosis and treatment has life changed for you? In what ways has life changed?'	PARTNERS2 'How does schizophrenia/bipolar disorder affect a person's life? What do they lose?' 'What outcomes are you/should we looking to achieve when delivering care or support to people with bipolar disorder/schizophrenia?' 'What are you looking to improve in the person's life?' 'Are different outcomes important to patients at different stages in their illness? At different stages in their health? Controlled versus stable? Diagnosis versus later management?'
CONSENSUS 'What's a good day like for you? What's a day like which is not so good' 'What would you say your priorities are in life at the moment? What would you have said if I'd asked that question before your illness and treatment?'	
mOMEnt – Discussion with parents: 'What do you think grommets (VTs) or hearing aids (HAs) should do for a child with glue ear?' mOMEnt – Discussions with children: 'What was "good" and "not so good" about VTs or HAs?'	

provided the basis for later discussions about which of the points discussed they felt were relevant to measure as outcomes in a research setting.

Focus groups or interviews?

If the purpose of qualitative research prior to a Delphi survey is to identify a complete list of outcomes which may be important to stakeholders, then a data collection method that allows the patient's journey to be understood may be most effective. However, if the purpose is to define the scope of the outcomes or the language, then an approach that allows convergences and divergences between different stakeholders to be identified may be most appropriate. However, often the objective of pre-Delphi qualitative research is to inform both a complete list and increase understanding of outcomes, which may call for a mix of qualitative data collection methods. Focus groups and one-to-one interviews are two ways in which qualitative data can be collected. These two methods of data collection have important differences which need to be considered when identifying outcomes in COS development.

In a one-to-one interview, data are generated through an interaction between the interviewer and the participant. A semi-structured format helps to ensure that the most important aspects are covered, while allowing the participant flexibility to explore concepts important to them. As described above this may involve participants giving an account of their illness and treatment experience, which researchers can interpret to identify outcomes which are important to patients.

In a focus group, data are generated through an interaction between the participants which is facilitated by the researcher. Participants are in a position to listen, discuss, agree, question or clarify points that are raised by other participants in the group. This synergistic discussion aims to facilitate participants in exploring outcomes which are important to them or the people they care for. Group discussion can help patients to see how their experiences differ to those of other participants in the groups and thereby help to identify outcomes which are important to them, or to challenge outcomes which are not important to them. However, there are drawbacks too. The logistics of completing groups can be challenging. Just as some people will dislike the idea of participating in an individual interview and prefer being part of a group, others may perceive a group discussion as intimidating and inhibitive. Additionally, a typical focus group involving 8–9 participants and lasting 90–120 minutes provides each individual with an average of only 10–15 minutes of speaking time, which can constrain the range of outcomes discussed.

Our experience of using focus groups in COS development indicates that while outcomes were discussed in depth, fewer outcomes were identified and understanding the patient journey and outcomes of importance at different stages was difficult. To address this challenge in PARTNERS2 we used a number of methods to collect non-verbal data, where participants were given the opportunity to write down outcomes of importance to them on slips of paper or 'post-it' notes. These data were then either used to inform discussion later in the focus group or were collected solely as written data. In some instances this exercise was designed to hide the identity of the note's author to allow sensitive outcomes to be identified and subsequently discussed without embarrassment or inhibition.

Analysis of data

When analysing the data from a qualitative study to support COS development, a focus must be maintained upon the particular purpose of the research. If, as described above, the main purpose of the research is threefold (to identify outcomes, define the scope of outcomes and identify common language) this must be reflected in the analysis. In many cases analytical approaches that code, label and index data will facilitate the process of identifying relevant outcome domains for the Delphi. Paying attention to, and maintaining the language of, the study participants will allow identification of common language. This should be part of an interpretive process whereby analysts consider the data as a whole in identifying relevant and understandable outcomes.

In the CONSENSUS study, for example, the coding, labelling and indexing of data, allowed the identification of the fact that patients tended to talk at length about the impact of treatment on aspects of their quality of life and how in contrast, survival was often mentioned only in passing or indirectly. One interpretation might be that survival was less important to these patients than aspects of their quality of life. However, considering the data and the interview as a whole the CONSENSUS team's interpretation was that issues of life and death were difficult for patients to talk about. In the context of interviews where patients were describing the months of unpleasant treatment that they had endured to improve their chances of surviving the illness, the importance of survival did not need to be laboured.

Future research

The use of qualitative research in the development of COS is increasing. This paper has described the potential benefits of qualitative research, indicated some of the challenges faced and provided examples of methods which may help to overcome them. The advice and guidance provided in this paper, which is not intended to be prescriptive, is based largely on the authors' experiences

of using qualitative research in the context of wider COS development projects. A better understanding of the role and contribution of qualitative research in COS development will depend on future methodological research. The following areas are identified as in particular need of such research.

Methods of data collection

More knowledge is needed on the differences in data collected from one-to-one interviews versus those collected from focus groups. As noted above our experience suggests that differences may arise; however, the nature and impact of differences on what is learnt and the associated resource use is not clear without further exploration. By reflecting on the use of qualitative data collection methods in COS development exercises to date, future research can be designed to assess whether interview and focus group data yield the same depth of meaning and understanding about stakeholder preferred outcomes and the extent and implications of any differences. Of course this cannot be considered in isolation from the points below.

Discussing outcomes

The way that outcomes are introduced to research participants and the framing of the discussion that follows will likely have a notable impact upon data collected. Research into the best ways to discuss outcomes with patients, carers and healthcare professionals – and whether to avoid overt discussions of 'outcomes' altogether – would help to ensure that participants are able to fully contribute to COS development process [29].

Analysing data

It is essential to understand the approaches to qualitative analysis that will be most informative for COS development. The need to go beyond a simple cataloguing of outcomes to form a deeper understanding of what participants wanted from treatments was identified in each of the COS development examples provided here.

Sampling

Understanding the impact of different sampling techniques is essential. As noted above, based on our experience, maximum variation sampling seems to be most likely to identify potentially important outcomes. However, confirmation of this and the potential effects of convenience or opportunistic sampling is vital.

Use of existing qualitative research

There is a large and expanding qualitative research literature on a wide range of different conditions and treatments and there are likely to be several such studies in particular disease areas that could potentially contribute to COS development, or even avoid the need to collect new qualitative data, which can be resource-intensive. Where qualitative datasets are available, secondary analysis of these may similarly negate the need for primary data collection, although research is needed to examine the extent to which such data, which will likely have been collected for very different purposes, can be used to inform COS development. Future research about how to usefully incorporate these data into COS development is of importance.

Conclusion

The use of qualitative research in the pre-Delphi stage of COS development is a novel methodological advance which brings a number of potential benefits. These benefits all relate to the primary goal of ensuring that all stakeholder perspectives are represented in the final COS, whether through identification of outcomes, understanding the importance of outcomes or identifying patient and carer language. Our experience suggests that with these benefits come a number of challenges. This paper suggests a number of potential methodological solutions, which we hope will be investigated further by researchers in this field.

Abbreviations

COS: core outcome set; PPI: patient and public involvement; RCT: randomised controlled trial.

Competing interests

The authors declare that they have no completing interests.

Authors' contributions

All authors have made substantial contributions to the conception and writing of this paper and have seen and approved the final draft. TK led the writing of the paper. TK, BY and PC provided detailed information of methods used. BY, JM and LLJ provided expert advice and guidance on qualitative methodology. PW provided detailed advice on continuing and ongoing COS development, methodology and standards. JJ provided advice on previous and ongoing COS development and their use of qualitative methods. MC provided expert advice on trial methodology and trial outcomes.

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